

WIPO
Standing Committee on the Law of
Patents

Exclusions from Patentability and
Exceptions and Limitations to
Patentees' Rights

A Study Prepared by

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Terms of Reference

At the thirteenth session of the Standing Committee on the Law of Patents, held in March 2009, it was decided that the Secretariat would “commission external experts [to conduct] a study on exclusions, exceptions and limitations focused on, but not limited to, issues suggested by members, such as public health, education, research and experimentation and patentability of life-forms, including from a public policy, socio-economic development perspective, bearing in mind the level of economic development.” (document SCP/13/7, para. 9(c)(i).

At the fourteenth session, held between January 25 and 29, 2010, a more elaborated terms of reference were announced as follows (SCP/14/INF/2):

“(a) The study shall be focused on, but not limited to, issues relating to public health, education, research and experimentation and patentability of life forms, including from public policy, socio-economic development perspective, bearing mind the level of economic development.

(b) The study shall include at least the following:

- (i) overview of the exclusions from patentable subject matter and exceptions and limitations of the patent rights at the international level;
- (ii) exclusions, exceptions and limitations relating to the legal conception of technology, such as patent protection of software-related inventions and life-forms;
- (iii) exclusions, exceptions and limitations where incentives through exclusive rights are unnecessary or incentives are provided by alternative protection mechanisms;
- (iv) exclusions, exceptions and limitations intended to avoid inhibiting further research and innovation;
- (v) exclusions, exceptions and limitations reflecting conflicts between patents and other social values, public policies and fundamental rights; and
- (vi) an executive summary of the study.

(c) The Study should cover, inter alia, the following subjects: (i) public health; (ii) education, research and experimentation; (iii) plants, animals and other life-forms; (iv) computer programs; and (v) biotechnology. Notwithstanding the above, the experts may agree on a different structure of, and distribution of the work relating to, the Study. In that case, the Coordinator of the study shall inform WIPO as soon as possible of the changes made.

(d) The Study shall take into account the statements made by WIPO Member States during the thirteenth session of the SCP, which are reflected in the draft Report of that session of the SCP (document SCP/13/8/Prov).

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EXECUTIVE SUMMARY

1. Nearly all patent systems contain either exclusions from patentable subject matter and limitations on the rights of patentees. This study seeks to survey such exclusions and exceptions and to explore the inter-relationship between them.
2. The Study was conducted in two stages. Firstly, regional experts produced reports on the relevant laws, jurisprudence and analysis by commentators in their regions. Secondly, the same experts took responsibility for synthesising the material in those reports into accounts relating to particular topics: computer programs, biotechnology, health, and research. This Study contains these latter reports.
3. The Introduction examines the history and rationales for various exclusions. The historical analysis suggests that while exclusions from patentability have a lengthy history, the existence of exceptions is a more recent phenomenon. The introduction also observes that there have been a growth in international norms limiting and standardising exclusions from patentability, but fewer provisions restrict exceptions.
4. The review of the rationales suggests a range of rationales for exclusions and exceptions. In many cases, these are of different sorts. In these cases, exclusions and exceptions do different jobs. However, in some areas, exclusions and exceptions have similar roles.
5. Where exclusions and exceptions are genuine alternatives, the Introduction suggests that the use of exceptions has not been fully explored. In many ways exceptions are likely to offer greater flexibility and nuance. The Introduction suggests that careful thought be given to broader use of exceptions, and counsels that efforts should be made so as to ensure international norms do not stifle this important avenue for calibrating national patent policy.
6. Chapter 2, authored by Professor Brad Sherman, considers exclusions relating to computer programs. He carefully explains how the different exclusions are interpreted in various regimes and the difficulties Patent Offices and courts have in finding adequate ways to differentiate between patentable and unpatentable subject matter. His survey did not identify any relevant exceptions targeted specifically at computer programs.
7. Chapter 3, authored by Professor Denis de Barbosa (with Kari Grau-Kuntz), examines exclusions and exceptions relating to life forms. It surveys the many exclusions for humans, animal life-forms and plants, and discusses the complex relationship between patents and plant variety rights systems (for example in relation to exceptions for farmers (the so-called 'farmer's privilege'). The author is cautious about reaching any conclusions in relation to developmental dimensions, in the absence of rigorous empirical study.

8. Chapter 4, authored by Professor Shamnad Basheer (with Shashwat Purohit and Prashant Reddy) surveys and reflects upon the exclusions relating to medicine. Key exceptions studied include those relating to methods of treatment and morality.
9. Chapter 5, authored by Professor Coenraad Visser, surveys and reflects upon the exceptions and limitations relating to medicine particularly the exceptions relating to pharmaceutical preparations, parallel imports and regulatory review ('Bolar provisions') and compulsory licensing of patents for purposes of protection of public health. The bulk of the chapter is concerned with the latter topic, and encompasses both an analysis of the international limitations (Article 31 of TRIPs and the Doha Waiver), a typology of different approaches in national laws, and selected case-studies where national authorities have granted compulsory licences in relation to pharmaceuticals..
10. Chapter 6, written by Professors Richard Gold and Yann Joly, examines exclusions and exceptions relating to promote research and teaching. The authors take a very broad approach, and virtually all exclusions from patentability (not just discoveries, scientific theories, mathematical methods) are able to be conceived as creating a "science commons" that facilitates research. Gold and Joly go on to examine in detail the operation of various exceptions that promote research, including experimental use exceptions, Bolar exceptions and prior use rights. Finally, the authors conclude with some general observations (including some comments on the relationship between patent law provisions and economic development).

1. INTRODUCTION

Professor Lionel Bently*

A. PRELIMINARY MATTERS: DEFINITIONS, BACKGROUND AND METHOD

Nearly all patent systems contain either exclusions from patentable subject matter and limitations on the rights of patentees. This study seeks to survey such exclusions and exceptions and to explore the inter-relationship between them.

Before we proceed any further it is useful to clarify our terms:¹

1. By “**exclusions**” we are referring to exclusions from the subject matter or patents no matter how novel or inventive a particular example within the exclusion may be. Common examples are the exclusion of abstract theories, or discoveries, or methods of treatment. In other words we are concerned with the limits to the domain of patentability (or “statutory subject matter”): questions of whether some product or process is eligible for protection.²

As we will see, it is not always easy to differentiate between “exclusions” from patentability, the positive requirement identified in many jurisdictions explicitly of an “invention”, and the related requirement of utility or industrial applicability. Indeed, some jurisdictions contain categorical exclusions of subject matter that in other jurisdictions might be assessed (and rejected) on a case-by-case basis as lacking inventive step or providing insufficient disclosure.

2. By “**exceptions**” from patentees’ rights we are referring to “limitations” on those rights. A good example is a limitation excusing from liability uses, which otherwise would violate a patentee’s rights, because they are uses in research or education. These are variously referred to as “exceptions”, “defences”, “permitted acts”,³ “free uses”, “restrictions”, or, by some commentators, “users’ rights”. We also include within the concept of exceptions situations where a person can use the subject matter of a patent on payment of a fee. These are usually referred to as “compulsory licences”, “non-voluntary licences” or “statutory licences”.

* With thanks to Yin Harn Lee, LLM (Cambridge, 2009-10) for research work; and to Brad Sherman for his valuable comments on an early draft of this chapter.

¹ See, also, Basheer, ch. 4 below.

² “[T]he subject matter that is eligible for patent protection.”: *Parker, Acting Commissioner of Patents and Trademarks v Flook*, 437 US 584, 588 (1978, US S Ct) (Justice Stevens); id at 600 per Justice Stewart (“subject matter patentability”).

³ Cook, Johnson & Roughton, *The Modern Law of Patents* (2010).

The study was commissioned by WIPO in the autumn of 2009. The terms are set out above. The decision to call for a study followed the creation of a report from the Secretariat.⁴ The Report of the Secretariat contained a very valuable collection of data on the patent laws of 98 countries and 5 regional arrangements, and we have relied on it as a valuable basis from which to build our report. Because this study has different goals, not all the information or insights provided by that Report are repeated here. We recommend therefore that this study be read in conjunction with the survey and analysis carried out by the Secretariat.

The topic of this study is an unusual one. Treatments of patent law tend to look at patent law as a whole, or to choose specific topics or sectors (for example, biotechnology). In studies of specific topics, questions of “subsistence” of rights and exceptions as to their scope are typically kept distinct. For example, WIPO has commissioned a host of studies on copyright exceptions generally,⁵ or examining specific copyright exceptions, such as those for libraries,⁶ for print disabled,⁷ and education.⁸ This study was commissioned, it appears, with a different premise. That premise is that “exclusions” and “exceptions” represent *different* mechanisms for implementing the *same* (or related) underlying policy goals. A particular jurisdiction, troubled by granting full patent rights over particular subject matter is faced with a choice: exclude that subject matter from patentability or permit patentability but address the concerns through exceptions to the rights granted to the patentee.

In order to explore this connection, we have tried to obtain information about the rationale or purpose of the exclusions and exceptions (as understood in legislative histories, commentaries and case-law). This has not always proved straightforward. Often provisions are unexplained. Sometimes, they are explained, but those explanations are multiple, shifting over time, or conflicting. That is, they are subject to very different interpretations by different tribunals. A good example of this is the divergence in the interpretation of the exclusions contained in Article 52 of the European Patent Convention. According to the EPO’s Technical Board of Appeal, the exclusion relate to material which is “abstract, intellectual and lacking technicality.”⁹ They concern, in effect, the definition of invention.¹⁰ In contrast, the Court of Appeal of England and Wales has expressed the view that ‘the categories are disparate with

⁴ WIPO, Report of the secretariat.

⁵ Sam Ricketson, *WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment* (WIPO, 2003) SCCR 9/7.

⁶ Kenneth Crews, *Study on Copyright Limitations and Exceptions for Libraries and Archives* (WIPO, 2008), SCCR 17/2.

⁷ Judith Sullivan, *Study on Copyright Limitations and Exceptions for the Visually Impaired* (WIPO, 2007) SCCR 15/7.

⁸ Joseph Fometeu, *Study on Limitations and Exceptions for Copyright and Related Rights for Teaching in Africa* (WIPO, 2009) SCCR 19/5; Victor Nabhan, *Study on Limitations and Exceptions for Copyright for Educational Purposes in the Arab Countries* (WIPO, 2009) SCCR 19/6; Daniel Seng, *WIPO Study on the Copyright Exceptions for the Benefit of Educational Activities for Asia and Australia* (WIPO, 2009), SCCR 19/7; Raquel Xalabarder, *Study on Copyright Limitations and Exceptions for Educational Activities in North America, Europe, Caucasus, Central Asia and Israel* (WIPO, 2009) SCCR 19/8.

⁹ See below: Sherman.

¹⁰ See, e.g., T154/04 *Duns Licensing* [2007] EPOR (38) 349, [29] (practical scientific applications v. intellectual achievements in general).

differing policies behind each. There is no reason to suppose there is some common factor (particularly abstractness) linking them.¹¹

As we will see, in some circumstances, as with “methods of treatment”, the use of an exclusion may well be regarded as an alternative device to the use of an exception. So we see that, while in Europe, such subject matter is not patentable, in the United States practising doctors are protected by an exception. A similar approach has been taken in the United States to the patenting of “business methods”. Once the Court of Appeal for the Federal Circuit had affirmed the validity of such patents in the *State Street Bank* case, Congress intervened to ensure that businesses were protected by way of an exception.

In other cases, as, for example, with the exclusion of computer programs from protectability in certain legal systems, there is much less evidence to suggest that the objections to patentability of computer programs are met through the provision of exceptions to patentee’s rights. That said, we agree with the premise underpinning this study that much is to be learned from thinking about alternative mechanisms for effecting the same policy goal. Thus although little consideration has, as yet, been given to specific exceptions from a patentee’s rights that protect the user of a computer program that itself has been, in some way or other, the subject of a patent, there might well be something to be said for such exceptions.¹² Users of programs who find themselves in a mesh of different intellectual property rights (copyright, patents etc), and a mesh of patents might gain significant comfort from the assurance that certain activities are never infringing.

Where “exclusions” and “exceptions” constitute *alternative* responses to the same policy goal, interesting questions arise as to which mechanism is “optimal” or, indeed, whether there are advantages to be had in using both. What are the advantages of “exclusions” over “exceptions”? What are the disadvantages? What are the advantages of exceptions over exclusions? What are the disadvantages? In answering these questions, we acknowledge that the matter is not merely an abstract one. The answer about “optimality” may reflect not just the legal and bureaucratic structures but also the socio-economic status of a particular country. What is an optimal arrangement for the US is not necessarily optimal for India or Malawi. This is true in relation to the question of the existence of a patent system at all, just as much as in relation to the details of any such system that is adopted. The appropriate emphasis may reflect a host of legal, economic and cultural considerations: the propensity of patent agents to formulate claims to avoid exclusions; the capacity of the patent offices to screen *ex ante*; accessibility of the legal system (for those wishing to challenge granted patents); the interpretive traditions of a particular country (such as whether exclusions are interpreted narrowly); the availability of alternative forms of

¹¹ *Aerotel* [2007] RPC (7) 117 para 9; para 30.

¹² Donald Chisum, *The Patentability of Algorithms*, (1986) 47 U Pitt L R 959, 1017-18 (recognising problems with allowing patents for software); Professors Dan Burk and Mark Lemley, for example, discussing US law, suggest that an exception be provided for reverse engineering, either through the experimental use or exhaustion: Dan Burk and Mark Lemley, *The Patent Crisis and How the Courts can Solve It* (U. Chi. Press 2009) 160-162 (noting that while historically the disclosure requirement would have made such provision superfluous, this is not the case with computer implemented inventions where it is not required that source code be disclosed).

protection (such as the use of trade secrets and confidentiality); the extent to which licensing is a realistic option for users, researchers; and so on.

Of course, as soon as the link is forged between “subject matter” and “exceptions”, other links become immediately visible. One is that between the “thresholds” of protection and exceptions. While all countries require that inventions are “new” before they can be patented, international law provides considerable leeway for national laws to define the concept of “novelty”. Different conceptions of novelty (or its opposite, “prior art”) vary as regards the place, time, and nature of relevant disclosures. Where novelty is defined by reference merely to disclosures to the public, the potential exists for secret prior users to find that the continuation of what they were doing prior to a patent application may become, after grant, acts that fall within the patentee’s rights. Regimes that have such standards frequently protect such prior secret users by giving them personal rights to continue their prior use. Such an exception would be unnecessary where such prior use could invalidate the patentee’s grant.

Similar observations might be made in relation to other aspects of patent law. Historically, one classic example has been the varied treatment offered where a patentee fails to exploit the subject matter of the patent. In some regimes, such failure rendered the patent liable to revocation. However, under the influence of international law, in particular, today the same concerns tend to be given expression through the grant of compulsory licences allowing third parties to work the invention.¹³ Another example relates to the definition of the patentee’s rights and exceptions. Some regimes limit rights, so that there is only infringement where the use is commercial. Others provide exceptions for “private and non-commercial use.” In principle, these are just two mechanisms that might be utilised to achieve the same end. In practice, however, (and depending often on the jurisprudential tradition or assumptions of the judges), the different placement of a policy within a particular legal system can have significant effects on its interpretation or application.

In short, intellectual property laws are themselves complex arrangements – to utilise a simile deployed by Professor Daniel Gervais when discussing copyright law, IP regimes are like “hydraulic systems.”¹⁴ Modifying one component may require adjustment of others if the components are to continue to work effectively. And the place of a particular component within the system may affect how it is able, or permitted, to operate. Moreover, as US Professors Dan Burk and Mark Lemley have articulated, different elements within the patent system comprise “policy levers” that can be adjusted to ensure the system accommodates different characteristics of invention from sector to sector.¹⁵

¹³ Jerome Reichman With Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions* (U.N. Conference on Trade & Dev. (UNCTAD) Issues Paper No. 5, 2002).

¹⁴ Daniel Gervais, ‘The Compatibility of the Skill and Labour Originality Standard with the Berne Convention and TRIPs Agreement, (2004) 26(2) EIPR 75.

¹⁵ Dan Burk & Mark Lemley, ‘Policy Levers in Patent Law,’ (2003) 89 *Virg Law Rev* 1575, 1642 (identifying nine such ‘levers’ including the exclusion of abstract ideas, utility, and the experimental use exception from patentee’s rights) ; Thomas Cotter. ‘A Burkean Perspective on Patent Eligibility, Part II: Reflections on the (Counter) Revolution in Patent Law (2010) 11(1) *Minn. J. L. Sci & Tech* 365, 379 (recognising various policy levers as additions or alternatives to patent eligibility); John F. Duffy, ‘Rules and standards on the Forefront of Patentability,’ (2009-10) 51 *Wm & Mary L. Rev.* 609

The lines of this study have thus been drawn rather arbitrarily, in as much as it is only concerned with two such policy levers.¹⁶ Some cutting off points are inevitable, of course, and the analysis of the inter-action “exclusions” and “exceptions” represents one of the most important questions in modern international patent law. Moreover, we believe this Study is valuable for the following reasons:

- (i) This study should provide valuable information about the state of the law over the world. It is 22 years since WIPO’s Committee of Experts on Patents systematically examined the exclusions from patentability. The 1987 study, reviewed below, covered 97 countries. Today, a decade and a half after TRIPs, a different picture emerges.
- (ii) Secondly, this study provides new analysis in so far as it goes further than reporting on the positive laws to tease out policy-rationales that underpin them. Little consideration has been hitherto given to a number of common exclusions from patentability, such as those relating to scientific theories. Our evidence shows that there is more to these exclusions than might have been appreciated: they play a significant role in preserving a public domain of science.
- (iii) Third, this study comes closer than any previous study to thinking about patent law in a manner which is sector specific. By examining the exclusions and exceptions as they apply to computer programs, life-forms, medicine and research, this study raises, implicitly if not explicitly, questions about whether the structural features of patent law respond, or ought to respond, to sector-specific matters.¹⁷
- (iv) Fourth, we hope that the study will provide guidance to countries considering reform. It is important to know what other countries are doing and how different countries reconcile a desire to incentive research with a concern not to stifle innovation through over-protection, a desire to maximise innovation without prejudicing public health, as well as a desire to comply with international obligations while simultaneously giving effect to local cultural, developmental and other priorities.
- (v) Fifth, this report attempts to say something about the relationship between exclusions, exceptions and socio-economic development. A broad study of this sort does not provide room for much more than collection of existing data (on which we found very little) and informed speculation about

(discussing inter-relationship between patentability, non-obviousness, disclosure requirement and exceptions).

¹⁶ Particularly in that we are asked to survey “patentability” but not “utility”, and “prior use” but not “novelty.”

¹⁷ These questions have been raised by US Law Professors Dan Burk and Mark Lemley: ‘Policy Levers in Patent Law,’ (2003) 89 *Virg Law Rev* 1575 (arguing that different sectors of invention require differently calibrated patent law and arguing for this tailoring to be achieved through adjustment of multiple “policy levers”).

what might be a desirable regime of patent law for countries at different stages of development. The arguments, are, in fact finely balanced and do not offer clear guidance as to the approach taken to any particular exclusion or exception.

- (vi) Finally, we hope to highlight important considerations for those involved in treaty formulation, such as those involved in the process of generating a substantive patent law treaty. The purpose of the study, however, is not to locate a core set of standards as to exclusions and exceptions on which there is substantial agreement (though such a common core does appear to exist). Rather, the aim of this paper is to remind those involved in treaty formulation that there are, at least in relation to some policy matters, different ways in which different jurisdictions give effect to particular policies. Care should be taken not arbitrarily to limit the use of different mechanisms when formulating standards applicable to either exclusions or exceptions. Treaty-makers need to keep in mind the interaction of different parts of the system.

Chapter 2, authored by Professor Brad Sherman, considers exclusions relating to computer programs. He carefully explains how the different exclusions are interpreted in various regimes and the difficulties Patent Offices and courts have in finding adequate ways to differentiate between patentable and unpatentable subject matter. His survey did not identify any relevant exceptions targeted specifically at computer programs.

Chapter 3, authored by Professor Denis de Barbosa, examines exclusions and exceptions relating to life forms. It surveys the many exclusions for plant and animal lifeforms, as well as exceptions for farmers (the so-called ‘farmer’s privilege)

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Chapter 6, written by Professor Richard Gold and Yann Joly, examines exclusions and exceptions relating to promote research and teaching. The authors take a very broad approach, and virtually all exclusions from patentability (not just discoveries, scientific theories, mathematical methods) are able to be conceived as creating a “science commons” that facilitates research. Gold and Joly go on to examine in detail the operation of various exceptions that promote research, including experimental use exceptions, Bolar exceptions and prior use rights. Finally, the authors conclude with some general observations (including some comments on the relationship between patent law provisions and economic development).

There are some inevitable overlaps between the chapters. Chapters 3, 4 and 6 all of which include material on exclusions from patentability of methods of medical treatment, while Chapters 3 & 6 both deal to some extent with lifeforms.

B. HISTORICAL DEVELOPMENT OF EXCLUSIONS AND INTERNATIONAL AND REGIONAL STANDARDISATION

Exclusions from the subject matter of patents have a lengthy pedigree. The French law of 1844 excluded from protectability ‘pharmaceutical compositions or medicines of all kind,’ and ‘schemes and combinations relating to credit and finance.’ The Austrian law of August 1852, excluded from patentability ‘preparations of food, beverages, and medicines’, discoveries, scientific principles, or purely scientific theorems, inventions or improvements which cannot be worked for reasons of public health, morals or safety, or as being contrary to the general interest of the state, according to existing regulations. Article 6 of the Italian Patent Law of January 1864 specified that ‘inventions or discoveries relating to trade which are contrary to law, morals, public safety’, ‘inventions or discoveries not relating to the manufacture of material objects’, ‘inventions or discoveries of a mere theoretical nature’ and ‘all kinds of medicines’ were unpatentable.

Explicit exclusions have a less extensive history in the “common law countries.” These countries have tended to operate with a general rubric as to patentability, which has been flexibly interpreted over the centuries. In the countries which came to be influenced by the English law, patentability has tended to turn on interpretation of the phrase “manner of new manufacture”, the domain of monopoly grant preserved to the Crown by the famous Statute of Monopolies of 1623.¹⁸ This phrase was interpreted by the courts, for example, from the late eighteenth century as excluding from protection “principles...”¹⁹ and for a long time there was doubt that it even included processes.²⁰ It was only in the early twentieth century that a rule emerged that patents were not to be granted for methods of treatment. The Statute of Monopolies did, it should be observed, prohibit patents that would be “generally inconvenient”, and the statute laws of many of Britain’s nineteenth century colonies expressly provided for the annulment of patents whose operation proved contrary to the public interest (or, echoing the Statute of Monopolies, “generally inconvenient”),²¹ and a number specifically required a demonstration of “utility”.^{22]}

¹⁸ “any manner of new Manufactures...so as also they be not contrary to the Law nor mischievous to the State by raising prices of commodities at home, or hurt of trade or generally inconvenient.”

¹⁹ *Boulton v. Bull*, (1795) 126 ER 651. For an exhaustive treatment, see Justine Pila, *The Requirement for an Invention in Patent Law* (Oxford U.P. 2010) 25-108.

²⁰ Pila, 40-41.

²¹ Act No 15 of 1859, s. 16 (India) (“mischievous to the state, or generally prejudicial to the public”); An Ordinance for Granting exclusive Privileges to Inventors, 1859, Ord. No 6, s. 25 (providing for orders that a privilege cease where “the [privilege], or the mode in which it is exercised, is mischievous to the State, or generally prejudicial to the public”) (Ceylon); An Ordinance to regulate the granting of Patents in this Colony, No 13 of 1861, s. 11 (“contrary to law, or prejudicial or inconvenient to Her Majesty’s subjects in general”) (British Guiana); Ordinance No 3, 1879, to repeal Ordinance No 24 of 1877 and to make other provisions in lieu thereof for the issue of Letters Patent, s.18 (if proved to be “prejudicial to the public interests”) (Fiji).

²² Act No 15 of 1859, s. 15 (India); Ordinance No 3, 1879, to repeal Ordinance No 24 of 1877 and to make other provisions in lieu thereof for the issue of Letters Patent, s.4 (Fiji).

The United States offered a slightly different model, but again built round a general rubric. The Patent Act of 1793, echoed in slightly different form in the Patent Act of 1870 offered patents to “any person who has invented or discovered any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement thereof....”.²³ This broad definition was, to some extent qualified by judicially developed doctrines– the so-called “moral utility doctrine”,²⁴ and the exclusion from patentability of aspects of the “natural world”, discoveries,²⁵ “unembodied inventions”, “handiwork of nature”, medical inventions,²⁶ and “business methods.”²⁷ Recently it has become common in the United States to limit to three the exclusions: laws of nature, physical phenomena and abstract ideas, though this shift has not been uncontroversial. The majority of the US Supreme Court appeared to affirm this approach in its 2010 *Bilski* decision.

The statutory definition of patentability adopted in the United States was reproduced outside the United States. The Jamaican law (1857), for example, related to “some new and useful art, machine, manufacture, or composition of matter, not theretofore known or used within this Island, or some improvement in any invention or discovery”²⁸ Newfoundland, similarly, offered patents to those who discovered or made “any new and useful art, machine, manufacture or composition of matter not

²³ Patent Act of 1793, ch 11, s. 1 (US); Patent Act of 1870, ch 230, s. 24 (US). For reviews of the US history, see Joshua D. Sarnoff, *Shaking the Foundations of Patentable Subject Matter* (2008); Oren Bracha, *Owning Ideas*, (unpublished thesis 2005).

²⁴ *Lowell v Lewis*, 15 F Cas 1018 (CCCD Mass 1817) (“the law will not allow the plaintiff to recover if the invention be of a mischievous or injurious tendency... All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word ‘useful’, therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people or to promote debauchery, or to facilitate private assassination, is not a patentable invention.” See also *Evans v. Eaton*, 16 U.S. (3 Wheat.) 454, 519 (1818) (useful means “applied to a beneficial use in society, in contradistinction to ... injurious to the morals, health or good order... or frivolous or insignificant”). The proposition was qualified, if not rejected, by the US Court of Appeals for the Federal Circuit in *Juicy Whip Inc v Orange Bang Inc*, 185 F.3d 1364, 1366-67 (Fed. Cir. 1999) (application relating to drinks mixing machine designed to deceive consumers into thinking they were receiving a ready-mixed drink from the machine was acceptable.) Circuit Judge Bryson stated that “the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent year.”

²⁵ *Morton v. N.Y. Eye Infirmary*, 17 F Cas 879 (CCSDNY 1862) (“In its naked ordinary sense, a discovery is not patentable. A discovery of a new principle, force, or law operating, or which can be made to operate, on matter, will not entitle the discoverer to a patent.”)

²⁶ *Morton v. N.Y. Eye Infirmary*, 17 F Cas 879 (CCSDNY 1862) (patent for method of surgery involving administration of sulphuric ether to the patient to render the latter unconscious was invalid, but on basis that it involved new use of known substance); *Ex p. Brinkerhoff* (1883) reprinted in 27 J.P.O. S. 797 (1945) (“methods or modes of treatment of physicians of certain diseases are not patentable”). See John F. Duffy, ‘Rules and Standards on the Forefront of Patentability,’ (2009-10) 51 Wm & Mary L. Rev. 609, 634-7; Anon, ‘Revisiting the Compromise of 35 USC §287(c)’ (2007-8) 16 Tex Int Prop L J 299, 303-4 (reviewing history).

²⁷ *Ex p Abraham* (PO, 1869); *In re Patton*, 127 F.2d 324, 327-8 (CCPA 1942) (“It is sufficient to say that a system of transacting business, apart from the means of carrying out such system, is not...patentable subject matter”. The position was reversed famously with *State Street Bank & Trust Co v Signature Financial Group Inc*, 149 F. 3d 1368 (Fed Cir 1998). See Gerard Magliocca, ‘Patenting the Curve Ball: Business Methods and Industry Norms,’ (2009) Brigham Young University L.R. 875, 881-884 (reviewing history). See also, John Duffy, *ibid*; Giles Rich, *Principles of Patentability*, 28 Geo Wash L R 393, 393-4 (1960). But the exception has been rarely, if ever, invoke: Michael Fuelling, ‘Manufacturing, Selling and Accounting: Patenting Business Methods,’ 76 JPTOS 471 (1994).

²⁸ An Act for amending the Law for granting Patents for Invention, (1857), Ch 30, Section 1, First (Jamaica).

theretofore known or used.”²⁹ Lower and Upper Canada adopted the same definition in 1824 and 1826, and, in turn, in the Canadian Act Respecting Patents of Invention, 1869.³⁰ Nevertheless, Canadian law broke ranks, providing specific exclusions from patentability: “no patent shall issue for an invention having an illicit object in view, nor for any mere scientific principle or abstract theorem.”³¹

The table below illustrates the relative frequency of exclusions from patentability in 1883. Five caveats are in order in relation to the table. Firstly, it is based on a sample of laws collected together in English in 1883: the original texts have not been reviewed, so something may be lost in translation. Secondly, the table is based purely on express statute law, so takes no account of those countries where exceptions are developed through case-law. This means that it understates the number of exclusions that in practice existed in common law countries – Britain, the United States, and the British & US colonies. Thirdly (and related) the table does not consider the “positive” side of the subject matter equation – that is, how the country defines “patentable subject matter”/“the invention” in the first place. An exclusion for “purely theoretical principles”, for example, might well have been implicit in the positive criteria for patentability in the laws of many countries. Germany, for example, required that patent could only be granted for “new inventions which can be turned to account in trade.” Fourthly, and perhaps least significant, the table combines grounds of rejection with those of annulment. Fifthly, the table fails to acknowledge overlaps between exclusions: for example, exception for “prejudicial or inconvenient” is expressed at a broader level of abstraction compared with some other exclusions, and could encompass, for example, attempts to patent financial schemes.

²⁹ Title XV, Ch 54, sec 1 of the Consolidated Statutes of Newfoundland.

³⁰ S.C. 1869, c. 11, s. 6 (“Any person ... having invented or discovered any new or useful art, machine, manufacture or composition of matter, or any new and useful improvement on any art, machine, manufacture or composition of matter...”)

³¹ An Act respecting Patents of Invention, Act of 14th June, 1872, 35 Vict c. 26, s. 6.

Exclusions from Patentability c. 1883³²

Food, beverages	Austria; Germany; Italy (art 37); Luxembourg; Sweden
Pharmaceutical; medicines	Argentine Republic; Austria; Finland; France; Germany; Italy; Luxembourg; Spain; Sweden ³³ ; Turkey; Venezuela
Substances produced by chemical processes	Germany; Luxembourg
Financial schemes	Argentine Republic; France; Mauritius; Spain; Turkey; Venezuela
Those of a mere theoretical nature; Inventions not relating to the manufacture of material objects; Scientific principles or purely scientific theorems	Argentine Republic; Brazil; France (art 30); Italy; Turkey; Venezuela; Italy; Austria; Canada (s.6) ; Finland; Russia (art 80); Spain
Use of natural products	Spain
Contrary to morals	Argentine Republic; Brazil; Colombia; Finland; France; Germany; Italy; Luxembourg; Mexico; Turkey; Venezuela
Contrary to laws	Argentine Republic; Austria; Brazil; British Guiana; Colombia; Finland; France; Germany; Italy; Luxembourg; Mexico; Portugal; Sweden; Turkey; Venezuela
Contrary to public health or safety	Austria; Brazil; Colombia (art 8) ; Finland; France; Italy; Mexico; Portugal (art 632); Russia (art 87); Turkey; Venezuela
“Prejudicial or Inconvenient...”	British Guiana; Ceylon (s.25); India (s. 16); Trinidad; GB; Mauritius (s. 17); New Zealand
Implements of war	Russia
Detriment to Government revenues	Russia (art 87)

In 1987, WIPO’s Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions conducted a survey of laws of (then) 97 Paris parties and 9 non-Paris countries.³⁴ The survey was concerned only with “what fields of technology are excluded from patent protection”,³⁵ rather than exclusions from protection more generally. It therefore offers no details e.g. as to exclusions relating to discoveries or business methods. Nevertheless, the survey does

³² Based on A. & E. Carpmael’s *Patent Laws of the World* (London: clowes, 1885) (surveying 51 countries).

³³ Art 2 (permitting patents “for special methods of” making medicines or food.

³⁴ WIPO, Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions, Fourth Session, Geneva Nov 2-6, 1987, “Exclusions from Patent Protection: Memorandum of the International Bureau of WIPO, HL/CE/IV/INF1 Rev.1 reproduced in (1988) *Industrial Property* 192

³⁵ para. 2.

offer an indication as to the relative prevalence of certain forms of exclusion at the time.

Exclusions from Patentability c. 1987

Pharmaceutical Products	49
Pharmaceutical Processes	10
Animal species	45
Methods of Treatment	44
Plant Varieties	44
Biological Processes for the Production of Animals or Plants	42
Food Products	35
Food Processes	10
Computer Programs	32
Chemical Products	22
Nuclear Inventions	14
Micro-organisms	9
Cosmetics	2 (Bulgaria, Republic of Korea)
Fertilizers	2 (Mexico, Yugoslavia)
Agricultural Machines	1 (Thailand)
Methods of Agriculture	1 (India)

The most obvious change over the century is the proliferation of exclusions. More specifically, by 1987 many countries have exclusions for

- (i) methods of treatment
- (ii) animal varieties
- (iii) plant varieties
- (iv) biological processes
- (v) nuclear technologies
- (vi) computer programs.

A number of explanations can be offered for this expansion of the number of exclusions (and the standardisation of the menu of exclusions and the language in which they are couched). Some of these are social and some legal.

The most important social shift that occurred over the century may well have been in terms of what might be conceived as falling within the scope of patent law. It is, after all, only when matter might be regarded as “patentable” that exclusions from patentability become necessary. Although it is not easy to get to grips precisely with the nature of shifts in the perception of what might be patentable, it seems uncontroversial to suggest that a host of factors – some religious, some economic, some technological – which prompted the formulation of these exclusions.

Changing religious perspectives affect the domain of patentable subject matter in so far as they define understandings of how and where human intervention comes

to produce changes in the physical environment.³⁶ Areas such as agriculture and biology, once purely the domain of religion and providence have over the last few centuries increasingly been seen as areas over which human beings have control. As the capacity to intervene and control has become more widely recognised and accepted, so too has the idea that there are human “inventions”. Nevertheless, the impact of religious beliefs on patent law and practice can still be seen in approaches taken, particularly under notions of “ordre public” and morality, to patentability of contraceptives, abortifacients and inventions that involve the use of human embryos for industrial or commercial purposes.³⁷ In fact, some laws, such as that of Indonesia specifically leave open the possibility of excluding from patentability inventions contrary to “religious morality.”

The growing acceptance and changing nature of economic reasoning has similarly affected attitudes as to what can and should be patentable. There is now widespread recognition of the significance of technological innovation to wealth creation, and thus many economists accept the long-term dynamic benefits of short-term interference with the free-market. The resistance to patenting that was exhibited in the name of economic liberalism and free trade in the nineteenth century has given way to a much wider acceptance of the benefits of patenting. However, limits to patenting emerged in relation to activities that were not regarded as “economic” or which countries sought to insulate from market mechanisms. One explanation offered widely for the exclusion of “methods of treatment” from patentability was that medical provision was, or ought to be, outside the economic system.³⁸

But perhaps the most obvious non legal explanation for the expansion of exclusions is changes in “technology” itself. The century since 1887 witnessed huge shifts in technological capacity following breakthrough inventions and discoveries, most obviously in the fields of atomic energy, computing and biology. While each of these new fields has generated a whole host of new patentable subject matters, each has generated its own concerns and its own exclusions from patentability. So, for example, it was only with the development of genetic engineering that the possibility of “creating” or “inventing” new animals (and with that possibility concomitant social concerns). Many of the exclusions thus reflect reactions to changes in the technological possibilities that are foreseen.

Four legal considerations may also be said to have influenced these developments. The first was the Paris Convention which, while providing a critical framework for international patenting, imposed no significant limitations on what must be regarded as patentable or what can be excluded. As long as there is no-discrimination on grounds of nationality, the Paris Convention gave members of the Union freedom to adopt the exceptions they considered appropriate in national law. Article 4 quarter contains only one notable limitation on subject matter:

³⁶ Sarnoff, *Shaking the Foundations of Patentable Subject Matter*, cited in Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 *IDEA* 123 (2008).

³⁷ Perhaps most obviously, the provision in the EC Biotechnology Directive Art. 6(2)(c); EPC Rule 23d(c), Implementing Regulations to the EPC (introduced by (1999) *OJEPO* 437).

³⁸ See Basheer et al.

“The grant of a patent shall not be refused and a patent shall not be invalidated on the ground that the sale of the patented product or of a product obtained by means of a patented process is subject to restrictions or limitations resulting from domestic law.”

As Professor Straus has observed, “...for over 100 years the Paris Convention left it to the discretion of its member states to provide for patents for inventions in all fields of technology or to exclude certain fields...”³⁹ The decision as to exclusions has tended to occur via systems of influence and copying, rather than on the basis of “first principles” in each particular territory. Thus, as in the field of copyright, networks of influence that reflected historical links (and particularly traditions of colonisation) continue to inform the adoption and adaptation of particular aspects of patent law.

A second factor in the standardisation of a menu of exceptions adopted is, bizarrely perhaps, the Patent Co-operation Treaty. Although the Treaty established a system for the international application for national patents, and thus did not require substantive harmonization of national laws, indirectly the Treaty appears to have standardised a bundle of exclusions. This is because Rule 39.1 of the Patent Co-operation Treaty declares that International Search Authority is not required to search an international application if its subject matter falls within any of 6 categories:

- (i) scientific and mathematical theories;
- (ii) plant or animal varieties or essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes;
- (iii) schemes, rules or methods of doing business, performing purely mental acts or playing games;
- (iv) methods of treatment of the human or animal body by surgery or therapy, as well as diagnostic methods;
- (v) mere presentations of information;
- (vi) computer programs to the extent that the International Search Authority is not equipped to search prior art concerning such programs.

Given that ISA’s are not required to search in these areas, a number of countries appear to have taken the view that patents should not be granted under their national laws in the fields. Dr Justine Pila of Oxford University has recently provided useful insights into the way in which the PCT, though procedural in orientation, influenced the development of substantive law.⁴⁰

The third factor in the proliferation and standardisation of exceptions in this period was the process of development and expansion of the EPC. Indeed, as Dr Pila has indicated, the processes of formulating the EPC exerted a significant influence on the formulation of PCT. The EPC 1973 distinguished three sorts of exclusion: those which were not to be regarded as inventions, contained in a non-exhaustive list in Article 52 (and including discoveries, scientific theories, mathematical methods, methods of performing a mental act, playing a game or doing business, aesthetic

³⁹ *From GATT to TRIPs*, Straus 171.

⁴⁰ Justine Pila, *The Requirement for an Invention in Patent Law* (Oxford U.P. 010) 117-121.

creations, presentations of information and computer programs); those relating to biological subject matter and immorality, contained in Article 53; and that in Article 54, excluding methods of treatment from patentability as a result of their being deemed not “industrially applicability”.

The fourth factor has been the activity of WIPO itself. In particular, from 1979 the WIPO model law for developing countries has had a degree of influence.⁴¹ Article 112 of the model law states

- (1) For the purposes of this Law, “invention” means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.
- (2) An invention may be, or may relate to, a product or process.
- (3) The following, even if they are inventions within the meaning of subsection (1), shall be excluded from patent protection:
 - (i) discoveries, scientific theories and mathematical methods;
 - (ii) plant or animal varieties or essentially biological processes for the production of plants or animals, other than microbiological processes and the products of such processes;
 - (iii) schemes, rules or methods for doing business, performing purely mental acts or playing games;
 - (iv) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practised on the human or animal body; this provision shall not apply to products for use in any of those methods.

Section 118 allowed for governmental authority to add temporary exclusions.

As will be evident, these standards overlap considerably. Consequently, it is not always easy to identify which of these influences – the PCT, the EPC or WIPO’s Model Law – were most important. Nevertheless some laws bear “tell-tale” signs. Laws which exclude “methods of treatment” on the basis that they lack industrial applicability seem to have been influenced by the EPC. Those that exclude certain matter “even if they are inventions”, seem to have adopted the approach of the WIPO Model law.

1987-2010: PROGRESSIVE LIMITATION OF EXCLUSIONS

By 2010 the table of exclusions appears as follows. Once again some caveats are in order. First, the table is based on the WIPO Secretariat’s survey. That survey includes some “common law” exclusions, that is, exclusions articulated by the courts. Second, in some jurisdictions the list of excluded matter is non-exhaustive, and the list does not represent that. Third, even though some jurisdictions (such as the EPC) list exceptions to patentability, the way in which patentability criteria are interpreted and applied may mean that they rarely constitute threshold exclusions but rather inform the inventive step assessment. Fourth, the categories deployed are at various levels of abstraction: thus it may be that one country would exclude subject matter specified at a low level of abstraction within an exclusion couched differently (or at a

⁴¹ WIPO, *WIPO Model Law for Developing Countries on Inventions* (Geneva, 1979).

higher level). Thus “aesthetic creations” (one category) might include “ornamental works” (another), while “mathematical methods” might include “algorithms”. Mostly the categories in the table reflect the terms deployed in national law (though there is no scrupulous adherence to linguistic identity). Fifth, and related, a particular subject matter in one legal system might be excluded under one heading, whereas the same subject matter might be excluded elsewhere in a different legal system. In the United States, for example, there is no business methods exclusion nor method of treatment exclusion, but case-law indicates that some business methods and methods of treatment are excluded from patentability where they are, for example, abstract processes.

Exclusions from Patentable Subject Matter

Inventions contrary to law, public order, public policy, public interest and/or morality	84
Theories or principles	84
Mathematical Methods	80
Therapeutic, surgical and diagnostic methods for treating humans or animals	79
Schemes, rules, methods etc for performing mental acts and/or	75
Plant and animal varieties	70
Schemes, rules, methods etc for playing games	69
Schemes, rules, methods etc for doing business and/or economic activity	69
Computer programs and/or software	64
Aesthetic Creations	59
Presentation of information	57
Essentially biological processes for the production of plants and/or animals	57
Inventions detrimental to human, animal or plant life or health and/or the environment	22
Works commonly protected by copyright	22
Materials occurring in nature	18
The human body and processes related to it	15
Organisational and management methods	10
Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit, and animals resulting from such processes	9
Algorithms	9
Topographies of integrated circuits	8
Plans etc for buildings and land development	6
Nuclear substances and/or processes	6
New uses	6
Combinations or alterations of known products which do not function separately or produce a non-obvious result	6
Symbols, schedules and rules	5
Inventions for the protection of human, animal or plant health or life or the preservation of the environment	4
Designs	3

Abstract ideas, natural phenomena, laws of nature	
Contrary to Sharia law	2
Inventions Contrary to Laws of Nature	2
Ornamental works	2
Plant products	1
Invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties or traditionally known component(s)	1
Agricultural and horticultural methods	1
Biotechnological inventions which can be used solely for one particular plant or animal variety	1
Patents for pharmaceutical products and processes requiring the prior consent of the national agency	1

The period between 1987 and 2010 is characterised by a progressive restriction on exceptions. Once again, there are legal and non-legal explanations.

Changes in technology have also affected the areas regarded as suitable for patenting, or at least made old distinctions appear more arbitrary and difficult to justify. Even if there is a lengthy history of the exclusion of business methods from patentability, the capacity to automate many business methods and other schemes has made it difficult to say is precisely the justification for keeping such matters unpatentable. Even where formal exclusions remain on the “legal books”, Patent Offices find them increasingly difficult to police. Similarly, technology has altered the nature of the practices of doctors. Diagnosis is not just a matter of looking and talking to a patient, and frequently involves practices which in fact feel very technological: the use of magnetic resonance imagery, administration of colouring agents, the use of genetic testing kits. These technological development have changed medical practice, both by placing the practice of medicine in a much more obviously commercially-influenced context and raising real questions as to what (if anything) method of treatment exclusions should cover.

At the same time the widespread acceptance of economic liberalism (and neo-liberalism), particularly during the 1980s and 1990s and amongst US legal scholars and judges, has prompted serious expressions of doubt over the traditional exclusions from patentability. If the economic argument is correct, that patents incentivise investment in research and development, why have restrictions on patenting of computer programs or methods of medical treatment? Indeed, some commentators go so far as to say everything that reaches a relevant threshold of novelty and inventiveness should be patentable – and some courts, particularly the US Supreme Court in *Diamond v Chakrabarty* – have come pretty close to adopting that view.⁴² Moreover, new strands of economic theory (sometimes dubbed neo-liberal) point towards the economic benefits of propertization of almost all ideas in order to optimise their exploitation. Chicago-economist Edmund Kitch’s famous “prospect theory” has spawned widespread belief that patents (and intellectual property rights more generally) should represent a default position – and thus that even inventions (or perhaps, really “discoveries”) that are not “industrially applicable” should be subject to private appropriation.

⁴² Michael Risch, ‘Everything is Patentable,’ 75 *Ten L R* 591, 658 (2008).

INTERNATIONAL LIMITATIONS ON PATENTABILITY AFTER 1999: TRIPs AND ITS FLEXIBILITIES

These views of course fed into the TRIPs Agreement, and subsequently informed regional trading blocs. Here the key provisions is Article 27 of TRIPs.

Subject to the provisions of paras 2 & 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. Subject to para 4 of Art 65, para 8 of Art 70 and para 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.

Professor Straus referred to the TRIPs developments as producing “a veritable revolution in patent protection at a universal level.”⁴³ Central to that revolution was the substantive harmonization of patent subject matter requirement, through the principle that – with one or two exceptions – patents should be available “in all fields of technology.” In particular, the aim was to ensure that countries no longer excluded pharmaceutical products and processes from patent eligibility.⁴⁴ The effect, not surprisingly, was to dramatically alter the number and nature of the exclusions from patentability.

That said, the provisions in TRIPs contain explicit and implicit flexibilities, and it should be clear from the table that these are widely adopted. The most obvious implicit flexibility is that while Article 27 contains an obligation to make patents available in all fields of “technology”, the Agreement does not define “technology”. Thus, it seems, contracting parties have considerable wiggle room to exclude subject matter from patentability on the basis that it does not constitute an invention (or a invention in a field of technology).⁴⁵ So, it appears that parties can exclude from patentability discoveries, scientific theories, mathematical methods, aesthetic creations, methods of performing mental acts and methods of doing business on the basis that such subject matter as “technological”, “technical” or “inventions.” As Stoll et al have observed

“While the current provisions remain silent on this issue, the historical background arguably implies that the Members may still define what they deem to be a patentable invention and what not. With this in mind, Members have indeed considerable leeway in defining these criteria...”⁴⁶

⁴³ J. Straus, in F-K Beier & G. Schriker, *From GATT to TRIPs* (VCH, 1996) 178.

⁴⁴ C. Correa, *TRIPs: A Commentary* (OUP, 2007) 271 (“from the outset of the Round...the extension of patentability, particularly to pharmaceuticals...was a major objective of the proponents....The very existence of the TRIPs Agreement can probably be attributed to the active lobbying of the pharmaceutical industry...”)

⁴⁵ Correa, *ibid.*, 271-2 (“Members have been left room to define ‘invention’ within their legal systems, in good faith...”)

⁴⁶ P-T Stoll, J. Busche & K. Arend, *WTO: Trade Related Aspects of Intellectual Property Rights* (2006), 479 (“Taking into account the diverse national approaches of Members concerning the

In fact, given that the question of what constitutes technology is an evolving one, and one that is in many cases controversial, the better view must be that the requirement should not preclude an exclusion in national or regional law unless and until there is substantial international consensus on what is “technology”. For the moment, there could not be said to be such agreement that computer programs or animals or higher life-forms or isolated genes or cells fall within the definition of technology. In these fields, the WTO should offer a wide margin of discretion to define patentability in line with their own conceptions of technology.

Nevertheless, important questions about Article 27(1) remain unresolved. While the laws of many countries (such as those parties to the EPC or influenced by it) exclude subject matter such as “discoveries” or “scientific theories” on the basis that these are “not inventions”, the laws of many other countries exclude subject matter irrespective of whether the subject matter amounts to an invention. For example, the laws of Antigua and Barbuda and Sri Lanka, exclude such material from protection *notwithstanding* the fact that they are inventions, placing the exclusion of discoveries and scientific principles on a par with exclusion of methods of treatment, plant varieties and the like.⁴⁷ Yet other countries exclude such matters “*irrespective*” of whether they constitute inventions or not.⁴⁸ Indeed section 112(4) of the 1979 WIPO model law recommended just such an approach, excluding such matters “even if they are inventions within the meaning of subsection (1)”, shall be excluded from patent protection. These laws, on their face, purport to exclude material which amounts to an invention and thus (presumably) falls within a “field of technology”. Are they therefore incompatible with Article 27(1) of TRIPs? The better view must be that they are not. The interpretation of TRIPs should be a matter of substance rather than form, and if such an exception is in fact permitted where a country categories it as a non-invention, so also it should be permissible where there is no explanation within national law (and indeed where the exclusion purports to apply irrespective of whether the subject matter is technology).

If Article 27(1) offer some flexibility, Article 27(2) and (3) contain explicit exceptions for morality, methods of treatment, as well as certain biological inventions. The languages of these paragraphs suggest they were informed by the provisions of Articles 53 and 54 of the EPC 1973. More specifically, Article 27(2) provides that:

“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.”

Article 27(3) adds that

interpretation of the concept of discovery, it cannot be ruled out that discoveries may be classified as inventions within the meaning of Article 27.”)

⁴⁷ Act No 23 of 2003, s.2(2) (Antigua & Barbuda); Code of IP Law 2000, s. 59(3) (Sri Lanka).

⁴⁸ Barbados Patents Act 2001 (No. 18), s.11; Belize: Patents, Act (Ch. 253), 21/06/2000, No. 14, s.12(1).

“Members may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non- biological or microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.”

A further provision of TRIPs, Article 73, leaves open the possibility of national laws providing for exclusions of patentability in the field of armaments and nuclear technology. It states

“Nothing in this Agreement shall be construed to prevent a Member from taking any action which it considers necessary for the protection of its essential interests;
–(i) relating to fissionable materials or the materials from which they are derived;
–(ii) relating to the traffic in arms, ammunition and implements of war
–(iii) taken in time of war or other emergency in international relations...”

Taking advantage of this, the laws of Albania, Brazil, China, India, Mocambique and Portugal all include exclusions relating to the patenting of nuclear methods and/or products.

Overall, while TRIPs contains some flexibilities, its impact on the exclusions in national laws has been profound. Few laws now contain exceptions relating to food or medicines, while many laws take advantage of the flexibilities that are left. The effect has been one of general standardisation. That said, some tribunals have shown a willingness to interpret Article 27 narrowly. In *Classen Immunotherapies Inc v. Biogen Idec, GlaxoSmithKline and Merck & Co, Inc*,⁴⁹ Sweet DJ:

“Article 8.1 and 27.3 of TRIPs permit governments to incorporate public health concerns into their intellectual property laws and to exclude from patentability diagnostic, therapeutic or surgical methods as well as particular inventions on the grounds of public interest. As a result, invalidation of the patents in suit [which related to isolated DNA sequences] would constitute neither a constitutional violation nor a conflict with the United States’ treaty obligations.”

REGIONAL STANDARDIZATION POST-TRIPS

In the period after TRIPs a number of regional arrangements have emerged governing patenting, and these largely have increased standardisation (while mostly taking advantage of the flexibilities left by TRIPs).

⁴⁹*Classen Immunotherapies Inc v. Biogen Idec, GlaxoSmithKline and Merck & Co, Inc* (USCAFC, 2006).

Eurasian Patent Convention (1994)

The Eurasian Patent Convention, concluded in September 1994, reinforced the continued standardisation of certain exclusions.⁵⁰ Article 3 of the Regulations implementing the Convention replicates many of the exclusions in the EPC (discoveries, scientific theories and mathematical methods for performing mental acts, computer programs, presentations of information) but augments and recasts some others, for example “ methods of economic organization and management”, “symbols, schedules and rules”, “algorithms”; “topographies of integrated circuits” and “projects and plans for structures and buildings and for land development” and “solutions concerning solely the outward appearance of manufactured goods and aimed at satisfying aesthetic requirements.” Article 4 of the Regulations also excludes plant varieties and animal breeds, as well as “inventions, the commercial use of which it is essential to prevent, for the purposes of protecting public order or morality, including the protection of the life and health of people and animals or the protection of plants, or in order to prevent serious damage being caused to the environment. Interestingly, there does not seem to be an exclusion of methods of treatment.

The Andean Agreement

Article 15 of *Decision 486* of the *Andean Agreements* excludes from patentability as non-inventions

- a) discoveries, scientific theories, and mathematical methods;
- b) any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germ plasm of any living thing;
- c) literary and artistic works or any other aesthetic creation protected by copyright;
- d) plans, rules, and methods for the pursuit of intellectual activities, playing of games, or economic and business activities;
- e) computer programs and software, as such; and,
- f) methods for presenting information.⁵¹

The most distinctive feature is the broad exclusion of living matter. In addition, Article 20 declares that certain inventions are not patentable (taking advantage of the flexibilities in TRIPs art 27(2) and (3)):

- a) inventions, the prevention of the commercial exploitation which is necessary to protect public order or morality;
- b) inventions, the prevention of the commercial exploitation within the respective Member Country of the commercial exploitation is necessary to protect human or animal life or health or to avoid serious prejudice to plant life and the environment;
- c) plants, animals, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes;

⁵⁰ The Convention entered into force in August 1995. The parties to the Agreement were the Republic of Azerbaijan, the Republic of Armenia, the Republic of Belarus, Georgia, the Republic of Kazakhstan, the Kyrgyz Republic, the Republic of Moldova, the Russian Federation, the Republic of Tajikistan and Turkmenistan. See <http://www.eapo.org/eng/ea/about/members.html>.

⁵¹ *Ibid.*

d) diagnostic, therapeutic, and surgical methods for the treatment of humans or animals.

In addition, Article 21 specifies that products or processes already patented may not be the subject of new patents on the sole ground of having been put to a use different from that originally contemplated by the initial patent.

Cooperation Council for the Arab States of the Gulf (GCC) (1998)

The Patent Office of the Cooperation Council for the Arab States of the Gulf (GCC) was established in 1998. It excludes from patentability

- a) Discoveries, scientific theories, mathematical methods, and computer programs.
- b) Schemes, rules, and methods for doing business, performing purely mental acts, or playing games.
- c) Plant varieties and species of animals, and biological processes for the production of plants or animals, other than microbiological processes and products.
- d) Methods of surgical or therapeutic treatment of the human or animal body and methods of diagnosis applied to the human or animal body with the exception of products used in any of these methods.
- e) Inventions necessary to safeguard public order or morality, including the protection of human or animal or plant life and health, or to avoid serious damage to the environment.
- f) Inventions contrary to the laws of Islamic Shariya.

Most of these exclusion correspond to those under the WIPO Model Law and EPC, though the “ordre public/morality” exclusion is more elaborate and the exclusion of inventions contrary to Sharia law is distinctive.

Bangui Agreement (1999)

Patent law for the sixteen countries in the African Intellectual Property Organisation (OAPI) is governed by the Bangui Accord.⁵² Article 1 of Annex 1 to the Bangui Accord provides that ‘invention means an idea that permits a specific problem in the field of technology to be solved in practice’.⁵³ This is qualified by Article 6 which provides for the following catalogue of exclusions:

- (a) Inventions contrary to public policy or morality.
- (b) Discoveries, scientific theories and mathematical methods.
- (c) Plant varieties, animal species and essentially biological processes for breeding plants or animals, other than microbiological processes and products.

⁵² The African Intellectual Property Organization (OAPI) was formed by the adoption of a new convention signed in Bangui on 2nd March 1977. The OAPI consists of sixteen west and Central African countries, namely; Benin, Burkina Faso, Cameroon, Central African Republic, Chad Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal and Togo. Patent law under the OAPI is dealt with under the Bangui Accord.

⁵³ Article 1 Annex 1: Patents, Agreement Revising the Bangui Agreement of March 2, 1977, on the Creation of an African Intellectual Property Organization (Bangui (Central African Republic) 24 February 1999.

- (d) Schemes, rules and methods for doing business, performing mental acts or playing games.
- (e) Therapeutic, surgical and diagnostic methods for treating humans or animals.
- (f) Presentation of information.
- (g) Computer programs.
- (h) Ornamental works
- (i) Literary, architectural and artistic works and all other aesthetic creations.

Free Trade Agreements

Some further standardisation (this time by limitation of exclusions) can be attributed to the post-TRIPs deployment of bilateral treaties, particularly Free Trade Agreements, setting “TRIPs-plus” standards. The major players in promoting such arrangements have been the United States, the European Union and Japan. US FTAs have sought, where possible, to limit exclusions from patentability. These FTAs ritually reaffirm the obligation to provide for patents to inventions in all field of technology,⁵⁴ and in many require that plants are not excluded from patentability.⁵⁵ In some cases, the treaties remove the possibility (available under TRIPs) of exclusions for animals,⁵⁶ while others specifically require recognition of new medical use patents.⁵⁷ Moreover, some set a maximum standard for the industrial applicability requirement (reflecting the US notion of “specific, substantial and credible” utility.)⁵⁸

C. THE HISTORICAL DEVELOPMENT OF AND INTERNATIONAL AND REGIONAL LIMITATION ON EXCEPTIONS

Exceptions to patentee’s rights have a less impressive history. The “experimental use” defence in U.S. law has been dated to Justice Story’s famous judgment in 1813 in *Whittemore v. Cutter*.⁵⁹ There he famously declared... “it could never have been the intention of the legislature to punish a man, who constructed such a machine for purely philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”

The table below illustrates the relative frequency of exclusions from patentability in 1883. Three caveats are in order in relation to the table. Firstly, it is based on a sample of laws collected together in English in 1883: the original texts have not been reviewed, so something may be lost in translation. Secondly, the table is based purely on express statute law, so takes no account of those countries where

⁵⁴ US-CAFTA-DR, Art 15.9(1)| US-Chile FTA, Art 17.1; US-Jordan, art 4.17; US-Peru FTA Art 16.9; US-Singapore, Art 16.7.

⁵⁵ US-Bahrain, Art 14.8(2); US-Chile FTA, Art 17.9 (2); US-CAFTA-DR, Art 15.9(2); US-Jordan Art 4.17 (implicitly); US-Morocco, Art 15.9(2); US-Oman FTA, Art 15.8; US-Peru FTA Art 16.9(2).

⁵⁶ US-Morocco FTA, Art 15.9(2).

⁵⁷ US-Bahrain, Art 14.8(2); US-Oman, Art 15.8(1).

⁵⁸ US-CAFTA-DR Art 15.9; US Peru, Art 16.9(11).

⁵⁹ 29 F. Cas. 1120 (D Mass 1813) (No 17,600). See also *Sawin v. Guild* 21 F. Cas 554 (CCD Mass 1813) (No 12 391) (in order to infringe a defendant ‘s actions must be undertaken “with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.” *Poppenhausen v. Falke*, 19 Fed Cas 1048, No 11279 (CCSDNY 1861); *Poppenhausen v New York Gutta Percha Comp Co* 19 Fed Cas 1059, No 11283 (CCSDNY 1858).

exceptions are developed through case-law. Thirdly (and related) the table does not consider the “positive” side of the scope of right equation – that is, how the country defines infringing acts in the first place.

Exceptions from Patentee’s Rights, c. 1883

Foreign Vessels	British Guiana, British Honduras; Cape of Good Hope; Germany (Art 5); Great Britain (s. 43); Leeward Islands; Luxembourg (Locomotive engines); Natal; New Zealand; South Australia; Tasmania; Victoria
Prior use	Canada (s.7, foreign patents); Germany (Art 5); Luxembourg (art 5); Mauritius (s. 26); Sweden (art 16); US (?) (s.4899)
Government Use	Germany (Art 5); Luxembourg; South Australia (s.36)
Compulsory Licences for Non-working	GB(s.22)
Exhaustion	Italy (art 8, c.3)

Forfeiture for Non-Working, c. 1883

One Year from Grant	Austria; Belgium; Colombia; Denmark; Italy*
Two Years from grant	Argentine Republic; Canada; Finland; France (Art 32); Italy; Jamaica; Newfoundland; New Zealand; Portugal; Spain; Turkey
Three Years from grant	Barbados; Brazil; Germany; Liberia; Luxembourg (art 18); South Australia (s.48); Sweden
Within first quarter of term (variable)	Russia
One year interruption	Brazil; Colombia; Finland
Two year interruption	Argentine Republic; Austria; Turkey Canada; France (Art 32); Italy; Portugal
Importation	Turkey
Refusal to License	Germany (Art 11.2); Luxembourg
Failure to supply Govt	New Zealand (s.23(3))
Public Good	Portugal (art 618)

Today, a very different picture emerges. A number of the statutory exceptions have become more common. For example, “exhaustion” in some form or other, and ‘prior use’ now appear explicitly in the laws of many countries. But other exceptions, such as experimental use, not articulated in the statutory law of any of the patent systems we examined for 1883, is now the most widespread exception.

Exceptions in 2010 (Not Including Compulsory Licences)

Experimental/Educational Use	86
Prior Use	85
Acts on or concerning foreign means of transport which temporarily or	80

* For short term patent.

accidentally enter national territory	
Exhaustion	73
Acts for non-commercial/non-profit making purposes	71
Preparation of prescribed drugs, and related acts	54
Exploitation and/or expropriation by or authorised by the government for national purposes	44
Bolar Exception	27
Biological material put on the market by the patent holder, other than for propagation purposes	14
Use by farmers of reproductive material for own agricultural activity	9
Exploitation authorised to counter anti-competitive practices	9
Non-repeated use of biological material to obtain viable new material	6
Use in exceptional circumstances or <i>force majeure</i>	6
Use of an essential element of the invention by a person unaware that it was for that purpose	4
Use of biological material for the purpose of breeding new varieties	3
Objects and goods in transit through national territory	3
Products existing in the country before the filing date (priority date).	3
Acts not prejudicial to normal exploitation of the patent, or the interests of patent owner and third parties	2
Indirect uses of production processes to obtain other products	2
Other limited exceptions introduced at the reasoned request of a competent authority	1
A person who, after the lapse of a patent, has used the invention, or has made the necessary preparation for such use, may continue to use the invention in the same volume after the renewal of the patent	1
Use or sale of products obtained from a legitimate source but made and sold without authorisation of patent owner	1
Objects to be launched into space from French national territory	1
Non-commercial use of living material as an initial source of variation or propagation	1
Acts committed before patent grant unless the application was already published, or the person concerned knew, or had been informed in writing, that the application had been filed	1
Variants or mutants of living forms or replicable living matter which are distinctively different from the patented original and deserve a separate patent	1
Acts in good faith by public authorities related to enforcement of intellectual property laws	1
Use of biological material already existing in nature which is not necessary for the industrial application specified in the patent	1
Exploitation by any person in the public interest, after three years from patent grant, where the supply to home market is of inadequate quality or quantity or excessively expensive.	1
Exploitation in good faith or taking real and effective steps towards exploiting the invention by third parties in the interval between the patent owner's loss of rights and the reinstatement of the patent	1
Exploitation by third parties of the invention or part of the invention in respect of which protection has been renounced	1

Biological material obtained in the field of agriculture by chance or through an unavoidable technical process	1
Importation or entry of small quantities of non-commercial goods in personal effects of passengers or sent in small packages	1

Various influences can be said to have prompted this proliferation in exceptions. Once again, some are non-legal, some are legal.

Changes in Science, Technology and Society

Some commentators have attributed growing importance of exceptions to changes in the scientific, technological and economic environment. It is widely stated that changes in the nature of basic science have rendered more “basic science” patentable than previously was the case. The effect of this is to prompt an inquiry into whether the parameters of exclusions should be strengthened (so, for example, that the exclusion of discoveries is made more robust), or whether instead some of the desirable effects of keeping basic science free can be accommodated through exclusions. As a result, then, of the perceived change in “the nature of science,” many countries have sought to introduce or strengthen private use and experimental use exceptions so as to ensure access to the basic building blocks of science that formerly fell outside the patent regime.

Another “cultural” shift that has had an important impact on patent policy is the changed practices of research and education institutions in the developed world. Although patenting is usually thought of as the domain of industry, following the US lead, for at least the last few decades universities and research institutes have increased their involvement in patenting. Thus many universities now patent “basic research” and seek to license it, often through start-up and spin-off businesses.

Exceptions that Respond to New Subject Matter

Clearly, the growth in the number and types of exclusion in part reflects shifts in what counts as patentable subject matter. Medicines, chemicals, food are no longer eligible for exclusion from patentable subject matter, as a consequence in particular of the TRIPs Agreement. This has led, in part, to a migration to exceptions, most obviously the introduction of provisions allowing use of such materials during patent term to obtain regulatory approval (so-called “Bolar” exceptions), and compulsory licensing provisions (most notably regarding the supply of pharmaceuticals to developing world countries).

Other exceptions have developed where countries, such as the United States, have abandoned exclusions for methods of medical treatment and business methods. Although the exception is not a common one, section 287(c) of the United States Patent Act is of particular interest to this project. The provision indicates that a patent is unenforceable against a medical practitioner (or a related health care entity) where the infringement occurs during “a medical practitioner’s performance of medical activity.” The provision was introduced in 1997, and was largely a response to controversy that arose from the case of *Pallin v Singer*,⁶⁰ in which a surgeon had

⁶⁰ *Pallin v Singer*, 36 USPQ 2d 1050 (D Vt, May 1, 1995)

sought to enforce a patent he had obtained for a particular method of performing eye surgery characterised by making a particular shaped incision in a specific point of the eye. Following the controversy it was proposed to introduce an exception from patentability for medical treatment, but this was opposed by the biotechnology industry. Senator Bill Frist came up with the idea of utilising an exception instead and, despite objections the compromise was accepted.⁶¹

Section 273 of the US Patent Act (as amended by the First Inventor Defense Act of 1999) offers a defence to infringement of business method patents where the defendant can show it had used the business method at least one year before the application was filed. Dan Burk and McDonnell describe the provision as “opaque and nearly incomprehensible.”⁶² And there do not appear to have been any reported cases on the Act.

A similar migration is anticipated by commentators on patenting of computer implemented inventions. As some of the consequences of patenting such works become clear, commentators argue, it may be necessary to broaden existing exceptions (perhaps introducing a fair use concept) particularly to give full effect to fundamental rights of free speech.⁶³

Exceptions as responses to New Practices and New Subject Matter

The combination of “new practices” and “new subject matter” goes a long way to account for the “Bolar exception.” The “new practice” is the increasing use of regulatory approval mechanisms to protect the health of the public: requiring, for example, that pharmaceuticals be demonstrated to be safe and effective before marketing it permitted. These mechanisms have meant that the time from a decision to develop a particular product to its actual marketing can in many cases be substantial. Coupled with the expansion of patenting to cover fields such as food and medicine, the existence of such regulatory requirements raised the question whether a person can utilise a patented invention during the patent term in order to provide information to meet regulatory approval.

Some countries laws almost certainly could have been relied upon by a third party in order to gain regulatory approval during the term of a patent with a view to marketing the product once the patent lapsed. But the narrowness of the US experimental use defence would not do so, and famously prompted the creation of a specific defence relating to persons experimenting on a patented invention in order to acquire data needed to gain regulatory approval. These exceptions came to be named

⁶¹ Omnibus Consolidated Appropriations Act, 1997, Limitation on Patent Infringements Relating to a Medical Practitioner Performance of a Medical Activity, Pub L No 104-208, 110 Stat 3009, s. 616 (codified as 35 USC s. 287(c)). See, Weldon Havins, Immunizing the Medical Practitioner “Process” Infringer: Greasing the Squeaky Wheel, Good Public Policy or What? (1999) 77 U Det Mercy L Rev 51; Anon, ‘Revisiting the Compromise of 35 USC §287(c)’ (2007-8) 16 Tex Int Prop L J 299 (reviewing history).

⁶² Dan Burk and Brett McDonnell, ‘Patents, Tax Shelters and the Firm,’ 26 Va Tax Rev 981, 1003 (2007).

⁶³ Dan Burk, ‘Patenting Speech’, 79 Tex L Rev 99 (2000) (noting that computer software has been characterised as speech and considering the implications for the expansion of exceptions to patentee’s rights).

“Bolar exceptions” after the case that prompted the intervention of Congress.⁶⁴ Section 271(e)(1) states that

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

Similar “Bolar exemptions” now exist in many countries,⁶⁵ though in various forms. Some (like that in the United States) are confined to pharmaceuticals only,⁶⁶ while others are broader. The Canadian,⁶⁷ Egyptian,⁶⁸ Indian,⁶⁹ Israeli,⁷⁰ and Japanese exceptions,⁷¹ Jordan,⁷² for example, are not industry specific.

International and Regional Norms

The proliferation of exceptions has occurred in an environment of relatively limited international norms. Just as the Paris Convention did not control the exclusions from patentability, it also set no requirements positively as to the scope of protection a patent would afford or - negatively - on exceptions. The Convention did - and still does - contain limits on national laws of forfeiture and on compulsory licensing: Article 5A (which is directed at the “prevention of abuse” of patents). The latter are discussed in detail in Professor Visser’s chapter (Ch 5). But, these provisions apart, national laws were left with unlimited freedom to provide limitations on rights.

In fact, two provisions of international law even required recognition exceptions in relation to vehicles that enter foreign territory where their use or repair might amount to an infringement of patent rights in that state. Art 5ter of the Paris Convention provides two such exceptions.⁷³ One applies to ships, the other to aircraft or land vehicles, and in both cases the exceptions apply only where the vessel, vehicle or aircraft is temporarily or accidentally visiting a country. According to the ships exception, the use of devices in the body of the vessel, in the machinery, tackle, gear or other accessories is not to be considered infringing, provided that such devices are used there exclusively for the needs of the vessel. As regards vehicles and aircraft, it

⁶⁴ *Roche Products Inc. v Bolar Pharmaceuticals Co* 733 F. 2d 858 (Fed Cir 1984) (relating to use of a patented sleeping pill to gain regulatory approval from the Food and Drug Administration).

⁶⁵ Christopher Heath, ‘The Patent Exemption for “Experimental Use” in Clinical Trials, Germany, Japan and the US Compared,’ (1997) 22 AIPPI J 267.

⁶⁶ See e.g. the European Union Directive 2004/27/EC of March 31, 2004 (regulatory approval).

⁶⁷ Acts of obtaining required regulatory approval for manufacture, construction, use or sale of a product under Canadian or foreign law.

⁶⁸ Egypt (Acts for obtaining a licence to market a product after patent expiration).

⁶⁹ Act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development or submission of information required under any law that regulates the manufacture, construction, use, sale or importation of any product.

⁷⁰ Israel (“Experimental acts for obtaining a marketing license after patent expiration”)

⁷¹ Patent Law, Law No 121 of 1959, amended by Law No 220 of Dec 22, 1999, art 69(1) (“The effects of the patent right shall not extend to the working of the patent right for the purpose of experiment or research.”)

⁷² Jordan (“Use for scientific research, development and obtaining marketing permits.”)

⁷³ See Bodenhausen, Guide to the Paris Convention, 82-3; Roughton (et al), *The Modern Law of Patents*, 284-8.

is no infringement to use patented devices in the construction or operation of aircraft or land vehicles or of accessories to such vehicles.

The second exception derives from Convention on International Civil Aviation of 7 December 1944 (with some 190 parties), and is only applicable to aircraft that have “authorized entry” into the territory. Article 27 prohibits any claim for patent infringement being made against the owner or operator of such an aircraft on the basis that the “construction, mechanism, parts, accessories or operation of the aircraft” or the storage or use of spare parts is an infringement of any patent.

The Community Patent Convention

Moreover, regional mechanisms did less to standardise exceptions than exclusions. We have already seen how the menu of exclusions embodied in the European Patent Convention directly limited the options of members of the EPC, and associated territories, and came indirectly to have wide influence via the PCT, TRIPs and bilateral agreements. But the EPC contains no provisions on exceptions – because it is a treaty concerned only with the regulation of the grant of rights.

That is not to say that regional standardisation of exceptions has not occurred in Europe. Rather curiously, there has been some via the Community Patent Convention, even though the Convention (in two forms from 1975 and 1989) never made it into force. Nevertheless, the Convention provided a model for European countries that was widely adopted.

Article 27(b) of the Community Patent Convention 1979/Article 31 of CPC 1975 Limitation on the Effects of the Community Patent

“the rights conferred by a Community patent shall not extend to:

- (a) acts done privately and for non-commercial purposes;
- (b) acts done for experimental purposes relating to the subject matter of the patented invention...
- (c) the extemporaneous preparation for individual cases in a pharmacy of a medicine in accordance with a medical prescription nor acts concerning the medicine so prepared
- (d) the use on board vessels of the countries of the Union of Paris for the Protection of Industrial Property, other than the Contracting States, of the patented invention, in the body of the vessel, in the machinery, tackle, gear and other accessories, when such vessels temporarily or accidentally enter the waters of Contracting States, provided that the invention is used there exclusively for the needs of the vessel;
- (e) the use of the patented invention in the construction or operation of aircraft or land vehicles of countries of the Union of Paris for the Protection of Industrial Property, other than the Contracting States, or of accessories to such aircraft or land vehicles, when these temporarily or accidentally enter the territory of Contracting States
- (f) the acts specified in Article 27 of the Convention on International Civil Aviation of 7 December 1944, where these acts concern the aircraft of a State, other than the Contracting States, benefiting from the provisions of that Article.

Article 28 dealt with exhaustion.

The rights conferred by a Community patent shall not extend to acts concerning a product covered by that patent which are done within the territories of the Contracting States after that product has been put on the market in one of these States by the proprietor of the patent or with his express consent, unless there are grounds which, under Community law, would justify the extension to such acts of the rights conferred by the patent”

Article 37 also made provision for “prior users” to retain personal rights.

(1) Any person who, if a national patent had been granted in respect of an invention, would have had, in one of the Contracting States, a right based on prior use of that invention or a right of personal possession of that invention, shall enjoy, in that State, the same rights in respect of a Community patent for the same invention

(2) The rights conferred by a Community patent shall not extend to acts concerning a product covered by that patent which are done within the territory of the State concerned after that product has been put on the market in that State by the person referred to in paragraph 1, in so far as the national law of that State makes provision to the same effect in respect of national patents.

Most European countries (apart from Austria) incorporated these provisions into national law in anticipation of the Convention coming in to force.⁷⁴ For various reasons, this never in fact occurred. The latest, Revised proposal for a Council Regulation on the Community Patent includes an almost identical menu in Article 9, though it is supplemented by additional provisions on farmed saved seed, animal breeding and computer programs.⁷⁵ Article 10 deals with exhaustion and Article 12 prior use rights.

The CPC has not, however, had the same standardising influence on exceptions outside the Community as the EPC has in relation to exclusions. In part, this is because it was not adopted within the TRIPs Agreement.

WIPO Model Law

The WIPO Model Law of 1979 did, of course, contribute a certain level of standardisation. Section 136 set out the basic limitations, and section 137 a prior user right:

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

(2) The rights under the patent shall not extend to acts in respect of products which have been put on the market in the country:

(i) by the owner of the patent;...

⁷⁴ Holzapfel & J. Sarnoff, ‘A Cross-Atlantic Dialogue,’

⁷⁵ Council of the European Union, Revised Proposal for a Council Regulation on the Community Patent, 13706/09 (September 29, 2009).

(3) The rights under the patent shall not extend to the use of the patented invention on any foreign vessel, aircraft, spacecraft or land vehicle which temporarily or accidentally enters the waters, airspace or land of the country, provided that the patented invention is used exclusively for the needs of the vessel or in the construction or operation of the aircraft, spacecraft or land vehicle.”

Section 135 added:

Where a person, at the filing or, where appropriate, priority date of the patent application and in the country,

(i) was making the product or using the process which is the subject of the invention claimed in that application, or

(ii) had made serious preparations toward the making or using referred to in item (i), that person shall have the right, despite the grant of the patent, to exploit the patented invention, provided that the product in question is made, or the process in question is used, in the country by the said person, and provided that he can prove that his knowledge of the invention was not by reason or in consequence of acts committed by the owner of the patent or his predecessor in title or of an abuse committed with regard to the owner of the patent or predecessor in title. Such right cannot be assigned or transferred by succession except as part of the establishment of the said person.

TRIPs

The TRIPs Agreement introduced the first significant limitations on the exceptions that a Member State can maintain, both via Article 30 and indirectly through the principle of non-discrimination as to the field of technology. Nevertheless, as we will see, that leaves considerable room.

Article 30 states that

“Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties.”

This has become known as the “three-step test”, echoing Article 9(2) of the Berne Convention and Article 13 of TRIPs itself.⁷⁶ It has three requirements: the exception must be “limited”; it must not “unreasonably conflict with the normal exploitation of the patent”; and it must not “unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

The meaning of Article 30 was considered by the WTO Panel in *WTO Canada- Pharmaceutical Products*, (2000) WT/DS114/R. This case concerned two

⁷⁶ The initial, “Anell”, draft would have allowed “limited exceptions” with illustrative list – private use, scientific use, prior use etc. The Panel in WT/DS114/R para 7.70 states that “the negotiating records of the TRIPs agreement give no explanation of the reason for this decision.” However, commentators suggest that the United States wanted to restrict the scope of the Article whereas the EC favoured a catalogue. See P-T Stoll et al, *WTO-TRIPS* (2006) 537.

exceptions in Canadian patent law: the so-called “regulatory review” exception and the “stockpiling” exception. The former exception stated that

“s. 55.2(1). It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or county other than Canada that regulates the manufacture, construction, use or sale of any product”

In effect this was a broad Bolar exemption, which enabled a competitor to make all necessary preparations to compete with the patentee as soon as the patent lapsed. Absent such an exception, a patentee would have been able, practically speaking, to extend its monopoly beyond the patent term. This was because third parties would have to wait until the patent lapsed, then make the necessary tests and await regulatory approval. That would take months if not years, extending the patentee’s exclusivity accordingly. With the exemption, the competitor would not have to wait for regulatory approval, so could start competing sooner.

The second exception – the “stockpiling exception” was more unusual. Here the Canadian law stated

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

The Manufacturing and Storage of Patented Medicines Regulations 1993 set period as 6 months for patented medicines. The effect of this was that a competitor could actually manufacture a drug in advance of the lapse of the patent, and as soon as it lapsed would be able to exploit the market. The WTO Panel held that the Regulatory Review exception was acceptable under Article 30, but the stockpiling exception was not. The Panel discussed each of the three elements.

With respect to the requirement that an exception be “limited”, the Panel explained that “limited” has narrow meaning. The Panel observed that the term qualifies “exception” which by itself connotes a “limited derogation”. It thus reasoned that a limited exception implied a narrow exception – “one which makes only a small diminution of the rights in question.”⁷⁷ Moreover, in assessing whether an exception is “limited” the question is not the “economic impact” but impact on “rights”.⁷⁸ Nor was the assessment a matter of “counting” how many rights (Make, sell, import) were affected.⁷⁹ Applying this reasoning to the Canadian laws, the Panel concluded that the “Stockpiling exception” abrogated the patentee’s rights to make and use the invention entirely during the 6 months, and thus could not be described as “limited” (para

⁷⁷ WT/DS 114/R, para 7.30; also para. 7.44.

⁷⁸ Ibid, para 7.48. But cf. 7.35 (scope of rights includes post-patent market effects for “months” after expiry)

⁷⁹ Ibid para. 7.32. Nor, the Panel observed, is there a “hierarchy of rights” (eg sale being most important) (para 7.35).

7.35)⁸⁰ In contrast the “regulatory review” exception was limited (para 7.45): “the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded.”⁸¹ As far as the issue of “unreasonable conflict” with the “normal exploitation” of the patent, the Panel examined the concepts of “normal” and “exploitation.” Firstly, it defined “exploitation” as “commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent”.⁸² The Panel stated that the notion of “normality” involved both “an empirical conclusion about what is common...[and] a normative standard of entitlement.” Importantly, “normal exploitation” included the period of factual exclusivity after expiry (para 7.56), but not the exclusivity that a patentee might hope for as a result of the need for competitors to obtain regulatory approval. Not surprisingly therefore, the regulatory review exception did not conflict with normal exploitation. The stockpiling exception would have done, presumably, as the Panel had concluded that the natural period of de facto “exclusivity” following lapse of a patent that existed while competitors geared themselves up to compete was part of the “normal exploitation” of the patent.

Finally, the Panel considered the “legitimate interests” of the patentee and third parties. The EC, in its submissions, had claimed that “legitimate interests” meant “legal interests”. The WTO Panel rejected this.⁸³ Instead, the Panel suggested that “legitimate” meant “‘justifiable’ in the sense that they are supported by relevant public policies or other social norms.”⁸⁴ Having so found, the key question for the “regulatory review exception” was whether the post-term benefits which would accrue to a patentee as a consequence of the delay involved in a third party having to seek regulatory review were “justified” for example, as compensation for the patentee’s own loss of capacity to take advantage of patent because it had had to do experiments and await regulatory review? Not surprisingly, the patentees would argue that as they lost valuable exclusivity during the patent when they were unable to exploit the invention, they had a legitimate interest in requiring third parties to wait until the patent lapsed before conducting its experiments to gain regulatory review. The problem, however, with this argument lay in the fact the sort of Bolar legislative deal (allowing experiments during the patent term, but giving the possibility to extend the exclusivity to compensate the patentee for its own “lost exclusivity”) had hardly become an international standard.

The Panel concluded the legitimacy of post-patent exclusivity was “a matter of unresolved political debate. On balance, the Panel stated,

“the interest claimed on behalf of patent owners whose effective period of market exclusivity had been reduced by delays in marketing approval was neither so compelling nor so widely recognised that it could be regarded as a ‘legitimate interest’...”

Although the Panel decision has been criticised by some, and doubtless needs to be read in the light of further developments within TRIPs (in particular the

⁸⁰ para 7.35.

⁸¹ para. 7.45.

⁸² para. 7.54.

⁸³ para. 7.68.

⁸⁴ para 7.69.

emphasis on public health in the Doha Declaration),⁸⁵ it seems to suggest a reasonable degree of flexibility to Member States in devising exceptions to patentees rights.

The Panel hinted that “experimental use” exceptions would be regarded as “limited exceptions.” Many countries operate some form of “experimental use” defence.⁸⁶ These tend to be defined – more or less broadly by reference to three parameters: the meaning of “experiment”; whether the exception extends to invention “with” or only “on” the patented invention; and whether the exception is available for commercial (as opposed to non-commercial) experimental activity.

The first question concerns what is covered by the “experimental use” exception. A number of variations present themselves: experimental use, “scientific research”,⁸⁷ “experiment or research”,⁸⁸ “research or development”,⁸⁹ “experimentation, teaching or scientific or academic research”,⁹⁰ “education, research, experiment or analysis”,⁹¹ “research or scientific experimentation purposes and manufacture, experimentation and testing of prototypes,”⁹² and, perhaps most elaborately, “private or academic scientific or technological research for non-profit making experimental, testing or teaching purposes.”⁹³

The second key distinction is between experimental use exceptions which permit experiment with the invention,⁹⁴ rather than those which limit the exception to experiments “on” the invention.⁹⁵ Most countries, it should be said, take the more restrictive approach, but some – most famously Belgium – allow experiment with the invention.⁹⁶ As for those common law countries where the exception is not in statutory form, we find that some, such as the United States, does not draw the

⁸⁵ Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), 14 November 2001

⁸⁶ See D. Gilat, *Experimental Use and Patents* (1995), 25. The US courts have occasionally employed the principle of *de minimis non curat lex*. See e.g. *Finney v. United States* 188 USPQ 33 (CCTD 1975).

⁸⁷ Barbados Patents Act 2001 (No. 18), s. 6(1)(a) “the use of the invention for scientific research only”.

⁸⁸ Albania; Armenia; Azerbaijan; Belarus; China; Japanese Patent Law No 121 of 1959, art 69 (“The effects of the patent rights shall not extend to the working of the patent right for the purposes of experiment or research.”) See Richard Jahn, ‘Experimental Use Exceptions: Changes in Research Tool Patent Protection in the United States and a Comparison to Japan,’ (2005) 30 Delaware Jo of Corporate L 925; Jennifer Johnson, ‘The Experimental Use Exception in Japan: A Model for US Patent Law?’ (2003) 12 Pac Rim L & Pol’y J 499.

⁸⁹ Bulgaria; Croatia.

⁹⁰ Bolivia (“Acts for experimentation, teaching or scientific or academic research.”)

⁹¹ Indonesia (“Use for purposes of education, research, experiment or analysis not prejudicial to the patent owner”).

⁹² Kyrgyz Republic.

⁹³ Argentina (“Private or academic scientific or technological research for non-profit making experimental, testing or teaching purposes”); Brazil (“Experimental acts for scientific or technological study or research”).

⁹⁴ Barbados Patents Act 2001 (No. 18), s. 6(1)(a) “the use of the invention for scientific research only”. Japanese Patent Law No 121 of 1959, art 69 (“The effects of the patent rights shall not extend to the working of the patent right for the purposes of experiment or research.”)

⁹⁵ Community Patent Convention. Costa Rica (“Acts done for experimental purposes relating to the subject-matter of the patented invention” and “Acts done exclusively for the purpose of teaching or scientific or academic investigation with respect to the subject-matter of the patented invention.”)

⁹⁶ Belgian Patent Act, art 28(1)(b) (enacted on April 25, 2005), discussed by G. van Overwalle, ‘The Implementation of the Biotechnology Directive in Belgium and its After Effects,’ (2006) 37 IIC 860, 906 ff.

distinction between experimentation on and experimentation with, while others – such as its neighbour, Canada – do.⁹⁷

Another key distinction is between those countries that permit experimental use even though there is a commercial purpose, and those that see experiment and commerce as contradictions in terms. The United States falls into the latter category, with its famously narrow research exception. In *Madey v Duke Univ*,⁹⁸ Madey, a patentee of free electron laser technology and former Duke Professor (until 1998), sued Duke University for using equipment which he had patented. Madey’s case was dismissed by the District Court who granted Duke summary judgment, but the decision was overturned by the US Court of Appeal for the Federal Circuit which remitted the case back to the District Judge. In so doing, the CAFC indicated that the exception for experimental use was “very narrow and strictly defined”. It encompasses acts performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry” and would not include experiment with a “definite, cognisable and not insubstantial commercial” purpose. Moreover, even where the user does not have commercial gain in mind, the exception would not apply if the act was “in furtherance of the alleged infringer’s legitimate business.”⁹⁹

It is certainly not clear that the broadest exceptions – defined along these three dimensions – would meet the Article 30 standard. At least one commentator has argued that the Belgian provision on experimental use, that allows experiment with as well as on the patented invention, might violate Article 30 on the basis that it does not constitute a “limited” exception.¹⁰⁰

TRIPs, Non Discrimination and Exceptions

As already explained, the TRIPs agreement introduced into international patent law the principle of non-discrimination as to the field of technology. This principle is established in Article 27 TRIPs both in a specific provision on patenting but also in a more general form in the second sentence:

Subject to para 4 of Art 65, para 8 of Art 70 and para 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

To what extent does Article 27, sentence 2, limit the permissible types of exceptions to patentees’ rights? And how does the principle interact with other provisions within TRIPs?

⁹⁷ *Micro-Chems Ltd v Smith Kline & Frech Inter-American Corp* [1972] SCR 506, 519-20; *Dableh v. Ontario Hydro* [1996] F.C 751, 781-2.

⁹⁸ 307 F.3d 1351 (Fed Cir 2002).

⁹⁹ *Ibid*, 1362.

¹⁰⁰ Wolrad Prinz zu Waldeck und Pymont, ‘Special Legislation for Genetic Inventions – A Violation of Article 27(1) TRIPs,’ in M. Adelman, R. Brauneis, J. Drexler, R. Nack, & Wolrad Prinz, *Patents and Technological Progress in a Globalized World : Liber Amicorum Josef Straus* (Springer, 2008) 289, 304, (suggesting the Belgian provision could hardly be regarded as a “limited exception.”)

Commentators have observed that there are at least two concepts of “discrimination.” At its broadest, “discrimination” might simply mean to “differentiate or make a distinction between”. If this were right, any exception that applied to one field of technology but not another would be impermissible. Alternatively, “discrimination” might to treat differently “on a basis other than merit.” According to the latter definition, exceptions would be permissible even if confined to (or targeted at) particular technological fields, where there was some “merit-based” reason to do so. The WTO Dispute Panel in its Report in the Canadian Pharmaceutical Products case adopted an approach akin to the latter:

“It [Discrimination] certainly extends beyond the concept of differential treatment. It is a normative term, pejorative in connotation, referring to the results of the unjustified imposition of differentially disadvantageous treatment.”¹⁰¹

Although, doubtless, a WTO Panel would scrutinise reasons offered for imposing a limitation confined to a particular field of technology, the better view appears to be that a wide margin of discretion should be offered to Member States. Exceptions should only be regarded as breaching the non-discrimination principle where it is evident, from the circumstances in which they were adopted or their inevitable effects, that they amount to illegitimate attempts to undermine the protection of particular subject matter that a country is obliged to provide.

There is precious little articulation of the relationship between these provisions. The second sentence of Article 27(1) states that it operates without prejudice to Article 27(3), which permits exclusions “from patentability” relating to methods of treatment, plant and animal varieties. Can we deduce anything from this derogation about the legitimacy of exceptions relating to medical treatment or plants? The US Patent Act, s. 287(c):(c) (1), contains an exclusion permitting use of patented medical methods. This specifies that

With respect to a medical practitioner’s performance of a medical activity that constitutes an infringement under section 271 (a) or (b) of this title, [no remedy should be available] against the medical practitioner or against a related health care entity with respect to such medical activity.

(2) ...(A) the term “medical activity” means the performance of a medical or surgical procedure on a body, but shall not include

(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent,

(ii) the practice of a patented use of a composition of matter in violation of such patent, or

(iii) the practice of a process in violation of a biotechnology patent.

The US Government was concerned that this was impermissible, in the light of the rule on non-discrimination as to the field of technology. The USTR argued that it was a violation,¹⁰² while others took the view that in the light of the provision allowing exclusions of “methods of treatment” from patentability, it must be

¹⁰¹ WT/DS114/R (Mar 17, 2000) para 7.94.

¹⁰² John Duffy, ‘Harmony and Diversity in Global Patent Law’, (2002) 17 Berk Tech LJ 685, at 722 (quoting USTR).

permissible to protect such subject matter but provide a specific exception in similar terms. The latter view in fact seems the more attractive.

TRIPs and Exhaustion

TRIPs also leaves Member States free to decide on the precise form of “exhaustion” Article 6 specifies that provisions in the agreement do not extend to exhaustion of rights (except for articles 3 and 4 that deal with discrimination based on citizenship). In some countries exhaustion is “international” extending to articles placed on the market “in any country.”¹⁰³ Others apply regional or national exhaustion.¹⁰⁴

TRIPs and Competition

A final observation on TRIPs that is worth making at this stage is that it leaves scope for Member States to adopt “consistently with the other provisions of this Agreement, appropriate measures to prevent or control” the abuse of intellectual property rights which have an adverse effect on competition. A number of countries expressly include exceptions permitting the exploitation of the patent by an authorized third party to counter anti-competitive practices, often conditioned on payment of remuneration.¹⁰⁵

POST-TRIPs REGIONAL ARRANGEMENTS

Several post TRIPs regional agreements have added a degree of standardisation to the exceptions, establishing a common menu of: private use, experimental use, prior use, exhaustion, as well as those relating to “transportation means”.

Eurasian Patent Convention

The Regulations under the Eurasian Patent Convention contain a series of exceptions to the rights conferred by a patent.¹⁰⁶ Under Article 19 the following are non-infringing:

1. Certain uses in relation to means of transportation that temporarily or accidentally enter the territory of an EAPO Member State.
2. Use for scientific research and experimental purposes.
3. Preparation of prescribed medicines in pharmacies.
4. Private use for non-profit making purposes.
5. Use of products put on to the market of a Contracting State by, or with consent, of the patent owner.

¹⁰³ Andean Pact, Art 54; Antigua, s. 11(4)(1)(a).

¹⁰⁴ The countries of the European Union, for example, apply regional exhaustion.

¹⁰⁵ See, in particular, the laws of Argentina, Australia, Barbados, Belize, Dominica, Pakistan, Papua New Guinea, the Philippines and Trinidad and Tobago.

¹⁰⁶ Eurasian Patent Convention, September 9 1994, rule 20.

Article 20 provides a “prior use” exception, and a similar exception for persons who used or made preparations to use an invention at a time when rights in the patent had lapsed.

Andean Pact

Article 53 of Decision 486 on Common Intellectual Property of 2000 provides the following exceptions to the rights of patentees:¹⁰⁷

- a) acts carried out in a private circle and for non-commercial purposes;
- b) acts carried out exclusively to experiment with the subject matter of the patented invention;
- c) acts carried out exclusively for the purposes of teaching or scientific or academic research;
- d) the acts referred to in article 5bis of the Paris Convention for the Protection of Industrial Property;
- e) where the patent protects biological material that is capable of being reproduced, except for plants, using that material as a basis for obtaining a viable new material, except where the patented material must be used repeatedly to obtain the new material.

Further exceptions are provided relating to “international exhaustion of rights” in Article 54 and “prior use” in Article 55.

Bangui Agreement

As already noted the Bangui Agreement of 1999, applicable in the countries parties to the OAPI, provides for a number of exceptions to the rights given to patentees.¹⁰⁸ Article 8 provides for the following exceptions:

1. Acts in relation to products put on to the market in an OAPI Member State by, or with consent, of the patent owner.
2. Use of objects on board foreign aircraft, land vehicles or ships that temporarily or accidentally enter the territory of an OAPI Member State.
3. Acts for experimental purposes in scientific and technical research.
4. Continued prior use by a person who in good faith, before the filing date (priority date), had exploited the invention in an OAPI Member State, or made effective and genuine preparations for that purpose.

Other provisions provide that the exploitation, by an administration or organization authorized by the Minister of the Member State concerned, for the purposes of vital economic interest, public health, defense or the country's needs, subject to remuneration.

¹⁰⁷ Decision 486, *art 53*.

¹⁰⁸ Bangui Agreement, Annex I (1999).

GCC

Patents Granted by the Patent Office of the Cooperation Council for the Arab States of the Gulf are subject to three significant exceptions

1. Continued prior use by a person who in good faith before the filing date (priority date), had manufactured, used the invention, or made serious preparations for that purpose.
2. Acts carried for scientific research purposes.
3. Certain uses in relation to means of transportation that temporarily or accidentally enter the territories of the Council States.

Free Trade Agreements

It does not appear that Free Trade Agreements have altered the landscape significantly. The US FTAs do in many cases include one limitation on the scope of the regulatory approval. Typically, this requires the party to limit the exploitation of products made legitimately under the regulatory review exception.

D. RATIONALES FOR EXCLUSIONS

In order to get to grips with the inter-relationship between exclusions and exceptions, it is clearly important to understand the rationales for each. This is not always an easy task. Laws, particularly statutes, rarely provide clear or detailed explanations as to what their provisions are intended to achieve. Instead this material tends to be located in the preparatory documents, commentaries and (particularly in common law countries) in the opinions of the courts interpreting and applying the doctrinal rules. In many cases we have found very little material to explain exclusions from patentability or exceptions to patentees' rights. Indeed, as the law of patents has become more globalized and underpinned by increasingly detailed international norms, it seems that less and less thought is given to the justification for individual legal provisions, and more and more to questions of adequate compliance. Perhaps not surprisingly therefore, discussion of rationales for particular rules seems most prevalent in those countries which appear to have had the largest roles in shaping the development of international norms.

The rationales that we have identified will, of course, not be regarded universally as persuasive. As the Board of Appeal of the European Patent Office noted (in relation to exclusions from patentability under the European Patent Convention):

“The categories of exclusions and exceptions may, depending on one's moral, social or other point of view, appear acceptable or unacceptable, quixotic or outdated, liberal or conservative...”¹⁰⁹

In particular, controversy surrounds the exclusions from patentability of methods of treatment, business methods and computer programs.

¹⁰⁹ T 315/03, *Oncomouse*, para 4.4:

The rationales that we identify are useful in aiding our task of understanding the relationship between exclusions and exceptions. But, of course, they are important in themselves because they influence how exceptions come to be interpreted within individual patent systems. Although a significant body of case-law had developed in Europe repeating the mantra that exclusions are to be narrowly interpreted, the Enlarged Board of the EPO has this principle does not apply ‘without exception’;¹¹⁰ G01/07, *Treatment by Surgery/Medi-Physics* (15 Feb., 2010) the EBA went even further and denied that there is any general principle that exceptions to patentability are to be interpreted restrictively. Rather “they are to be interpreted to give effect to their purposes.” In some circumstances, therefore, the rationale might justify a narrow interpretation, in other cases a broad interpretation.

Matters are, however, further complicated because different jurisdictions sometimes attribute different rationales to what appear on the surface to be in substance the same exclusions. A good example is the exclusion of “animals”. In Europe, this has been recognised as a matter of “public policy.” In contrast, in Canada, the Supreme Court excluded animals from patentability on the basis that they did not fall within the definition of invention, such as “compositions of matter”.¹¹¹ The countries of the Andean Community similarly appear to exclude “[a]ny living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing” from patentability because these are not inventions.

Another example relates to “discoveries”. In Europe, “discoveries” are excluded as “non-inventions” because they – like (most of) the other subject matter in Article 52 EPC are “abstract”, “intellectual” and “non-technical” in character. In contrast in the United States, the explanation for the exclusion is more explicitly policy oriented. In *Gottschalk v Benson*,¹¹² for example, the Supreme Court explained that the exclusion from patentability of natural phenomena, mental processes and abstract intellectual conceptions was explicable because these are the “basic tools of scientific and technological work.”¹¹³ In short, the explanation for the exclusion of discoveries in the EPO is “ontological”: from their very nature, discoveries are not inventions. In contrast, in the US ontology is less important than policy. Whether or not discoveries of naturally occurring phenomena might be classified as “inventions”, these matters are excluded from appropriation through patents because of their consequences. Being “the basic tools”, it is important to the progress of the useful arts that they are free for all to build upon (or with).

Different Rationales for Existing Exclusions

The different exclusions, not surprisingly, often have different rationales. From our survey we have identified six such rationales:

¹¹⁰ G01/04 para. 6. Note also *Aerotel* [2007], paras 12, 21-22 (principle that exceptions are to be construed narrowly was said to be inapplicable to Art 52).

¹¹¹ *Harvard College v. Canada (Commissioner of Patents)* [2002] SCC 76 (Supreme Crt of Canada).

¹¹² 409 US 63, 67 (1972).

¹¹³ But cf. *In re Meyer*, 688 F.2d, 789, 795 (CCPA 1982), citing *Leroy v Tatham*, 55 US 155, 175 (1852), the Court of Customs and Patents Appeals...: “scientific principles and laws of nature, even when for the first time discovered, have existed throughout time, define the relationship of man to his environment, and, as a consequence, ought not to be the exclusive rights to any one person”

- (a) exclusions that clarify what is understood by the term “invention”;
- (b) exclusions that reflect problems internal to the patent system;
- (c) exclusions that reflect the fact that protection is afforded elsewhere;
- (d) exclusions that exist because no legal incentive is required;
- (e) exclusions in relation to inventions that are positively undesirable;
- (f) exclusions that recognise countervailing policy considerations (outside the patent system)

(i). Exclusions that clarify what is understood by the term “invention”

Some legal systems define the term “invention”. In Antigua & Barbuda,¹¹⁴ for example, an invention is defined as “an idea of an inventor which permits in practice the solution to a specific problem in the field of technology and an invention may be, or relate to, a product or a process.” In Japan, an invention is a “highly advanced creation of technical ideas by which a law of nature is utilized”.¹¹⁵

In Mexico an “invention” is defined as ‘Any human creation that allows matter or energy existing in nature to be transformed for utilization by man for the satisfaction of his specific needs shall be considered an invention.’¹¹⁶ Moreover in the United States, section 101 of the Patents Act 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 therefor, ...

Other systems offer no positive definition of “invention.” The most well-known of these is the European Patent Convention. According to some commentators it was simply too difficult for the different European countries to find a common definition of invention, each of the major parties having longstanding experience with their own particular characterisations (the requirement of “technical character” in Germany, “industrial character” in France and “manner of new manufacture” in the United Kingdom). Instead the EPC defines a non-exhaustive list of matters that are deemed not to be inventions. The “exclusions” from patentable subject matter, in effect, clarify the “positive” side of what is protectable. Other examples of this approach can be seen in the Andean Pact (Art 15 of decision 486), as well as the national laws of Algeria and South Africa.¹¹⁷

Even countries with positive definitions of invention often operate with exclusions, either express statutory exclusion or ones developed through the courts. In the United States, the Supreme Court declared that:¹¹⁸

¹¹⁴ Act No 23 of 2003, s.2(1)(ii). It seems this was influenced by the WIPO Model Law (1979). Article 112 of the model law states. For the purposes of this Law, “invention” means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology.”

¹¹⁵ Japan, Art 2(1): ‘a highly advanced creation of technical ideas by which the law of nature is utilised’

¹¹⁶ Article 15 (Mexico).

¹¹⁷ Article 6 of the Algerian Patents Ordinance 19/07/2003 - 1424, No. 03-07; South Africa Patents Act No 57 of 1978.

¹¹⁸ *Diamond v Chakrabarty*, 447 US 303; *Diamond v. Diehr*, 450 US 175, at 185 (1981); *Laboratory Corporation of America Holdings v Metabolite Laboratories, Inc* (2006), at 126 (Breyer J).

“Einstein could not patent his celebrated law that $E=MC^2$; nor could Newton have patented the law of gravity. Such discoveries are manifestations of nature free to all men and reserved exclusively to none.”

The exclusion of discoveries (where the use of the discovery is unknown) has also been explained on the related ground that the subject matter lacks utility or industrial applicability. In the famous US case of *Brenner v. Manson*,¹¹⁹ for example, the plaintiff, Manson, claimed to be entitled to protection for a novel process of making a known steroid but the Patent Office denied his claim on the ground that the chemical compound produced by the process lacked “utility”. The Supreme Court: “A patent system must be related to the world of commerce rather than to the realm of philosophy...” Most recently, the Supreme Court in *Bilski* has confirmed the three exclusions of “laws of nature”, “physical phenomena” and “abstract ideas”, though this shift has not been uncontroversial.¹²⁰ Whether these are simply exclusions because the matter is not an “art, machine, manufacture or composition of matter” is less clear. Although on its face, this looks like a question of interpretation, it should be observed that the structure of US law links issues of “the nature” of the subject matter inextricably with public policy. The US Constitution only permits the grant of exclusive rights to inventors for their “discoveries” [i.e. inventions] where to do so would promote the useful arts. Any determination of patentability has potentially both an “ontological” dimension and a public policy underpinning.

(ii). Exclusions that reflect policy-decision within other parts of the patent system

Sometimes exclusions from subject-matter patentability in fact reflect policies that might better be considered elsewhere in the patent system, for example under novelty, non-obviousness, or disclosure. Professor Duffy provides some interesting examples of these from US patent history: the exclusion of “new uses” as a matter of patentability, he suggests, reflects the absence of standards of non-obviousness, while the exclusion of lifeforms reflected difficulties with disclosure.¹²¹ The exclusion of “abstract principles”, he argues, reflects, in fact, the requirements of disclosure, which has “migrated” into section 101. The categorical exclusions from patentable subject matter was thus not a question of “principle”, but rather reflected a desire for categorical clarity:

“When the very nature of the alleged invention makes it impossible to satisfy the Patent Act’s disclosure requirements, that problem might be better expressed as a patentable subject matter issue than as a failure of disclosure, for that characterization clearly indicates that the barrier to obtaining the patent lies in the nature of the alleged discovery, not simply in the words chosen by the applicant - ...to describe or disclose it.”

A similar approach may well explain the exclusion of computer programs from patentable subject matter. The decision to exclude computer programs from patentability was, at least in some commentaries, explained by reference to practical

¹¹⁹ *Brenner v. Manson*, 383 US 519 (1966) (US S Ct).

¹²⁰ *Bilski v Kappos* 561 US __ (2010).

¹²¹ John F. Duffy, ‘Rules and standards on the Forefront of Patentability,’ (2009-10) 51 Wm & Mary L. Rev. 609, 646.

difficulties of applying the patent system, such as searching and examination. As early as 1966, the U.S. President's Commission on the Patent System reported that:

“The Patent Office now cannot examine applications for programs because of a lack of a classification technique and the requisite search files. Even if these were available, reliable searches would not be feasible or economic because of the tremendous volume of prior art being generated. Without this search, the patenting of programs would be tantamount to mere registration and the presumption of validity would be all but non-existent”¹²²

Similar arguments were being ventilated during the 1990s in Europe and more recently in relation to software and business methods.¹²³ In a work with the attention grabbing title, *Patent Failure: How Judges, Bureaucrats and Lawyers Put Innovation at Risk* (2008) Professors James Bessen and Michael Meurer argue the difficulties examining patent applications relating to computer software and business methods, as well as difficulties in constructing clear boundaries around the subject matter of such claims, mean allowing patenting imposes significant costs on businesses. In an earlier foray into this territory, Michael Meurer argued that these sorts of problems would justify a categorical ex ante exclusion:

“cost-savings justify the exclusion of business methods ...because a proper non-obviousness analysis (based on the economic trade-off) would deny patents to most business method patent innovations.”¹²⁴

In Chapter 3 of this Report, Professor Basheer makes a similar observation about a number of exceptions that exist, *inter alia*, under the patent law of India: combinations of elements with no synergistic effect, second medical uses of known substances and derivatives of chemical substances with no “efficacy” are, he contends, excluded from patent eligibility in order to give effect to a desire for a heightened standard of novelty/inventiveness through a “bright line rule.” Similar rules can be found in the laws of Argentina, Bolivia,¹²⁵ Chile,¹²⁶ Columbia,¹²⁷ Costa Rica,¹²⁸ Ecuador,¹²⁹ Mexico,¹³⁰ Panama,¹³¹ Peru,¹³² and Syria.¹³³

¹²² Quoted in 409 US 63, 72 (1972).)

¹²³ D. Haselden, ‘The Practical Issues: A View from a Patent Office’, *The Patent Office Conference on Software Patents* (<http://www.patent.gov.uk/softpat/en/index.html>). These include (i) practical problems of searching ‘prior art’ given that there is no tradition of patenting software, (ii) lack of expertise, (iii) problems of breadth, and (iv) the problem of description.

¹²⁴ Michael Meurer, *Business Method Patents and Patent Floods*, (2002) 8 Wash U. J L & Pol’y 309, 334 n.132.

¹²⁵ Exclusion of “new uses”.

¹²⁶ Chile (“New uses of articles, objects or elements and changes of shape, dimensions, proportions or materials in which do not involve an essential alteration or solve a technical problem”).

¹²⁷ Exclusion of new use patents.

¹²⁸ Costa Rica (“Juxtaposition of known inventions or mixtures of known products, or alteration of the form, use, dimensions or material thereof, except where in reality they are so combined or managed that they cannot function separately, or where their qualities or characteristic functions have been so modified as to produce an industrial result not obvious to a person skilled in the art.”)

¹²⁹ New uses.

¹³⁰ Mexico (“Juxtaposition of known inventions or mixtures of known products, or alteration of the use, form, dimensions or material thereof, except where in reality they are so combined or managed that they cannot function separately, or where their characteristic qualities or functions have been so modified as to produce an industrial result or use not obvious to a person skilled in the art.”)

(iii). Exclusions that reflect the fact that protection is afforded elsewhere

Most patent systems exclude literary and artistic works from protection.¹³⁴ Some laws – particularly those of countries which are parties to the Eurasian Patent Convention go further and specify that integrated circuits, buildings and aesthetic designs are not protectable by patents.¹³⁵ One reason for doing so is because “aesthetic creations” are protected under copyright law. Indeed, the Andean Pacts decision on intellectual property hints at this rationale in the formulation of its exclusion: “literary and artistic works or any other aesthetic creation protected by copyright.”¹³⁶ The Eurasian Patent system seems to take a similar approach to subject matters that could be protected by trade marks (symbols) and designs law.

Why should the existence (or potential existence) of copyright, or there intellectual property, protection mean that subject matter is not patentable? Two reasons offer themselves. The first is that where copyright protection arises, there is no need for the additional incentives provided by patent law. Production is optimised without burdening society with additional exclusions. Alternatively, or additionally, it may be that protection by multiple intellectual property rights is regarded as unsatisfactory. According to some commentators, subject matter should be protected under one regime, but not more than one. Sometimes, reflecting this view, legal systems have excluded patent documentation from copyright protection, and refused trade mark protection to technical subject matter.¹³⁷

Some people find these rationales implausible because different intellectual property laws protect different aspects on intellectual products. This is most obvious in relation to the trade mark/patents interface, where patents prevent the making and selling of the invention itself, whereas trade mark rights only offer protection to the features of an invention that come to operate as trade marks, that is, to indicate trade origin. It is difficult to see why, once patent protection has lapsed, that trade mark protection should not be available: a competitor will not be prevented from selling the technical solution itself, as long as it does not do so in a way which confuses consumers about the origin of the goods. Equally, if different IP rights protect different aspects of products, it may well be that declining to protect some aspects of an intellectual subject matter will lead to inadequate incentives. Copyright law, for example, in most countries protects only the “expression”, the detailed configuration of words or symbols that constitute a work. It will not protect the underlying “ideas”, or “business logic”. To refuse patent protection just because an intellectual artefact is

¹³¹ Panama (“Combinations or alterations of known inventions and products which do not function separately or produce a non-obvious industrial result.”)

¹³² New uses.

¹³³ Syria (pharmaceutical combinations).

¹³⁴ European Patent Convention, art 52(b). The United States has operated a “printed matter” exception”: In re Ngai, 367 F. 3d 1336, 1338 (Fed Cir 2004) (printed matter teaching new use for an existing product does not render otherwise unpatentable use protectable, the court observing that if the position was otherwise “anyone could continue patenting a product indefinitely provided that they added a new instruction sheet to the product”)

¹³⁵ Law on Inventions, Utility Models and Designs 2008, Art 10(1)(g), (h), (i) (Armenia).

¹³⁶ Article 15 of *Decision 486*. See e.g. Bolivia (excluding from patentability “literary, artistic works and other works protected by copyright.”).

¹³⁷ Community Trade Mark Regulation, Art 7(1)(e).

also protected by copyright thus seems to have a dubious logic in cases where copyright and patents in practice protect different aspects of an intellectual product.

Nevertheless, there is no doubt that a proliferation of overlapping intellectual property rights presents potential distributors, users, developers of existing intellectual artefacts with a complex and perplexing picture. This is particularly so as other rules – formalities, the threshold of protection, qualification of non-nationals, ownership, the scope of rights, exceptions, and even remedies – are likely to vary from one IP regime to another. The exclusions, in their attempt to simplify this picture, may offer a practical – if not absolutely logical – solution to the social cost caused by the complex minefield of sophisticated legal rights.

Another exclusion whose appearance may be attributable to the existence of a different legal system of protection is the widespread exclusion of “plant varieties.”¹³⁸ As is well known, many countries offer “sui generis” protection to plant varieties (and, indeed, TRIPs, Art 27(3) requires that a country does so if it excludes plant varieties from patentable subject matter). These “sui generis” regimes for plant varieties are often informed by an international arrangement, the UPOV. Indeed, the 1978 UPOV contained a prohibition on dual protection of plant varieties, effectively requiring those countries that had plant breeders’ rights regimes to provide for an equivalent or co-extensive exclusion from patentability.

This prohibition has been abandoned in the latest version of UPOV. Nevertheless, many countries with establish plant breeders’ rights regimes, see much force in their maintenance. Such regimes usually have special requirement before protection is available (normally that the variety be demonstrated to be “distinct”, “uniform” and “stable”), frequently operate systems to test whether breeds meet these criteria, and offer breeders a limited regime of rights. Importantly, plant breeders regimes clarify that users, such as farmers, have a number of freedoms, particularly in relation to re-use of propagating materials.

The plant breeders’ regimes were developed largely before the arrival of modern biotechnology. This technology has radically altered the ways in which new types of plant can be developed. Often, plant inventions no longer relate merely to one variety: for example where genetic modification allows any plant grouping to be rendered resistant to a particular substance. At the same time, traditional plant breeding techniques continue to be used. The problem any legal regime faces is how to configure a suitable system of protection in this altered environment.

While some countries have allowed for overlapping of patent protection with sui generis plant breeders’ regimes, many have persisted in an attempt to keep the regimes as alternatives. The existence of a plant breeders’ regime would, some argue, be undermined if patenting of the same subject matter were permitted protection under the general patent law. This is because the patent regime would often confer stronger protection (though on the basis of an applicant meeting different criteria).

¹³⁸ Many countries exclude plant varieties from protection under patent law. In Europe, the European Patent Convention excludes “plant varieties” from the subject matter of patents. The European Union’s Biotechnology Directive Art 2(3) defines a “plant variety” as ‘a plant grouping within a single botanical taxon of the lowest known rank’, and the Directive clarifies that a plant-invention is patentable if ‘the technical feasibility of the invention is not confined to a particular plant variety.’

(iv). Exclusions that reflect patent law's cost-benefit analysis

Some matters are excluded from patentability because it is considered that the social costs of the legally enforceable rights outweigh the benefits. In carrying out this calculation, the social and economic context forms a crucial background. In particular, the level of inventiveness and disclosure that would occur even in the absence of a patent system is a significant consideration. So too, are the potential effects of the existence of patents on any existing non-legal incentives to create or disclose.

There may well be certain categories of invention where no artificial incentive is regarded as necessary to optimise investment. This is because social norms may provide some level of recognition, reward or protection, or sufficient economic incentives exist without interfering in the marketplace, for example, through lead-time. Much academic attention has started to be paid to such “social norms” offering protection to creators of intellectual productions outside of the intellectual property field, for example, within the social worlds of magicians, comedians and cooks.¹³⁹ Other, more obvious examples, have long-existed from the world of “pure science” and medicine, where much of the cost is publicly-funded and discoveries have often been recognised and rewarded with naming rights – for example, the right to name a planet or plant or have a scientific theory or medical syndrome named after one. Less prominently, many scientists obtain significant reputational rewards for the disclosure of their discoveries (with those reputational rewards often being translated into financial compensation through academic promotion and competition in the higher education sector for the best researchers). The existence of these sorts of social norms may form part of a calculation that patent rights are unnecessary, and possibly detrimental, to the successful operation of the field.¹⁴⁰ Hence, perhaps, the conclusion that discoveries, scientific theories and, possibly, methods of treatment are to be unpatentable. If optimal incentives exist outside the patent system, permitting patents adds only restrictions to the free flow of information.

These social norms provide an explanation on exclusions in many countries. In the United States, where, as we have seen, such exclusions are more limited, some have started to suggest that the existence of such social norms should affect the courts interpretation of the otherwise broad and open-ended definition of invention. Professor Magliocca of Indiana University has argued that “there should be a presumption against considering a process patentable subject matter... when a norm can be found in the relevant industry against patenting the class of innovations at issue.”¹⁴¹ In short, he suggests that the court should ask whether the “person having

¹³⁹ E.g. Jacob Loshin, ‘Secrets Revealed: How Magicians Protect Intellectual Property Without Law,’ (2007) SSRN; Dotan Oliar & Chris Sprigman, ‘There’s No Free Laughs Any More: The Emergence of Intellectual Property Norms and the Transformation of Stand Up Comedy,’ 94 Va L R 1787 (2008); Emmanuelle Fauchart & Eric von Hippel, Norms-Based Intellectual Property Systems: The Case of French Chefs (2006), SSRN.

¹⁴⁰ Thomas Cotter, ‘A Burkean Perspective on Patent Eligibility’, 22 Berk Tech LJ 855 (2007) “The principle that laws of nature and basic research should remain outside the patent system is also clearly rational, in light of both the potential for a contrary rule to generate enormous social costs and the availability of other time-honored means, such as direct government subsidies, for inducing basic discoveries.”

¹⁴¹ Gerard Magliocca, ‘Patenting the Curve Ball: Business Methods and Industry Norms,’ (2009) Brigham Young University L.R. 875, 877.

ordinary skill in the art” would consider the type of process at issue patentable.¹⁴² Magliocca sees his proposal as preferable to using categorical exclusions because definitional problems will be minimised, “the definition will be supplied by industry participants on a case by case basis.” However, as he himself acknowledges, the test is anything but predictable: while Magliocca suggests that business methods might be excluded, he remains uncertain how the test would apply to “software invention.” Importantly, for our purposes, the merits of the proposal do not matter so much as the insight that exclusions from patentability that exist in many countries, and, in Magliocca’s view ought to exist in the United States, should take account of sectoral norms, including existing “intellectual property without intellectual property rights.”

In other cases, lead-time may be a sufficient incentive. This is perhaps most obviously the case in relation to business methods, where it seems likely that market incentives to produce new, more efficient business methods are strong. Certainly, there has never, it seems, been a sense that a shortage of new and innovative business ideas exists, in the same way that societies recognise quickly the need for new medicines to counteract prevalent diseases (cancers, AIDS, malaria and so on). Another area where market norms seem sufficient incentives is with “user improvements” particularly in computing. Such innovation is likely to be motivated more by self-interest or by reputational norms) than by artificial patent incentives.¹⁴³

The “cost-benefit” analysis, though, is not just about excluding inventions that “would occur anyway.” It is also about recognising the costs that patents create – the social costs associated with deadweight loss, transaction costs and so on. In the field of computer programs and business methods, the transaction costs have appeared formidable – with widespread concerns emerging about “patent trolls” and “submarines”, as well as the complex relationship between patents and standards. There are many commentators in the United States who argue that in these fields the possible grant of patents overall imposes costs on society.¹⁴⁴ Professors James Bessen and Michael Meurer provide convincing evidence that the extension of patentability to encompass computer software and business methods has, for a variety of reasons, imposed greater costs on business than benefits.¹⁴⁵

But the costs that need to be weighed are not just the obvious economic ones: it also needs to be recognised that patenting have the potential to transform particular environments from ones that operate with certain communal, altruistic sharing norms to ones in which individual private gain is maximised. If “methods of treatment” constitute an example of a situation where there are (or have been) strong social norms incentivising creation and disclosure, it may also be an environment where the introduction of market norms has a serious affect on the benefits derived from those norms. Say, for example, that the diagnosis of certain illnesses might be greatly improved by doctors sharing informational resources concerning patients. Such a co-

¹⁴² Ibid, at 894. At 896 (“to ask whether that same reasonable member of a technical or business community would think that the claim genre is patentable subject matter.”)

¹⁴³ Strandberg has developed an interesting distinction between “user” and “seller” inventions: (2008) 79 U Colo LR

¹⁴⁴ Thomas Cotter. ‘A Burkean Perspective on Patent Eligibility, Part II: Reflections on the (Counter) Revolution in Patent Law (2010) 11(1) Minn. J. L. Sci & Tech 365, 379 (“the extension of patent eligibility to software and business methods has produced, on net, far greater social costs than benefits.”)

¹⁴⁵ *Patent Failure: How Judges, Bureaucrats and Lawyers Put Innovation at Risk* (2008).

operative arrangement is likely to be much less costly in an environment where all believe they have a mutual project of improving health outcomes, compared to one where the effect of sharing information is to facilitate one gaining monopoly rights over a particular method of diagnosis. In *Lab Corp of America v Metabolite Labs., Inc.*,¹⁴⁶ Breyer J in the Supreme Court of the United States summed up the issue:

“the reason for this exclusion is that sometimes too much patent protection can impede rather than ‘promote the Progress of Science and Useful Arts’, the constitutional objective of patent and copyright protection.”??

That said, while it is clearly important to take account of these subtleties when establishing a patent system, or determining its scope, this level of analysis is devilishly difficult. As Thomas Cotter has explained

“[t]he principal difficulty is that no one is sufficiently well-informed to know how to craft the patent eligibility requirement so as to maximise the surplus of social benefits over social costs...”¹⁴⁷

(v). Exclusions in relation to inventions that are positively undesirable

Some exclusions can be justified simply on the basis that there are certain categories of invention that it is undesirable to encourage. In such cases, it would be odd to offer artificial incentives to produce such inventions by granting patents. This category could have been subsumed within the cost-benefit analysis (Category D), in so far as these are inventions where there are deemed to be no positive benefits. But, because the “positively undesirable” quality of an invention is rarely thought of in terms of economic effect, we use a separate category.

The most obvious example of such subject matter relates to inventions the exploitation of which would be contrary to public policy or accepted principles of morality. In early US jurisprudence, the exclusion of immoral invention was regarded as the corollary to the requirement of utility. As Justice Story famously explained a ‘useful’ invention is one “which may be applied to a beneficial use in society, in contradistinction to an invention injurious to the morals, health, or good order of society, or frivolous or insignificant.”¹⁴⁸ Today, while the United States may have abandoned its “moral utility” doctrine, many countries exclude from protection “immoral inventions.” Sometimes this is by way of a general exclusion of immoral invention. Some countries use carefully drafted specific exclusions. For example as a

¹⁴⁶ 548 US 124, 126-7.

¹⁴⁷ Thomas Cotter. ‘A Burkean Perspective on Patent Eligibility’. 22 Berk Tech LJ 855 (2007) [text near n. 120]

¹⁴⁸ Notes on the Patent Laws, 3 Wheat App 13, 24. Cited in Brenner (1966) 383 US 519, 533. Lowell v Lewis 15 Fed Cas 1018 (No 8568) (CCDMass); Bedford v Hunt, 3 Fed Cas 37 (No 1217) (CCDMass).

¹⁴⁹ Japanese law, for example, declares that “inventions liable to contravene public order, morality or public health shall not be patented”: Patent Law of Japan, Law No 121 of 1959, amended by Law No 220 of 1999, Art 32 (Japan). Mexico excludes from patentability subject matter which is “contrary to public policy, morality or proper practice....”: Industrial Property Law, art 4 (Mexico). Chinese law excludes from patentability “any invention-creation that is contrary to the laws of the state or social morality or that is detrimental to the public interest”: Article 5 (as amended in December 27, 2008). See Margo Bagley, ‘The New Invention-Creation Activity Boundary in Patent Law,’ (2009-10) 51 Wm & Mary LR 577, 583.

consequence of the European Union's Biotechnology Directive, the Member States are obliged to exclude from patentability "processes for cloning human beings",¹⁵⁰ processes for modifying the germ line genetic identity of human beings,¹⁵¹ use of human embryos for industrial or commercial purposes,¹⁵² as well as 'processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.'¹⁵³

While such exclusions from patentability are common, they are not universal. Other countries operate with no "morality" exclusion. While the United States formerly included a morality exclusion in its application of the "utility requirement", this approach seems to have been abandoned. In *Diamond v. Chakrabarty* (1980) the Supreme Court referred to "a gruesome parade of horrors" that might result from genetic research, but said that these concerns were a matter for Congress, implying that the "morality" of an invention was irrelevant if the subject matter otherwise fell within the statutory clause.¹⁵⁴ One commentator explains that "[u]nder current law, there is no morality determination made at the USPTO and a patent examiner may not reject a patent application on moral grounds,"¹⁵⁵ though another notes that the USPTO has, nevertheless, stated that it will not grant a patent over a human being.¹⁵⁶ The Canadian Commissioner of Patents, similarly has "no discretion to refuse a patent on the grounds of morality, public interest, public order or any other ground if the statutory criteria are met..."¹⁵⁷

Some jurisdictions take the view that providing patents induces disclosure of these sorts of invention, which might be regarded as preferable to their exploitation in secret. A common objection to the exclusion from patentability of immoral subject matter is that it misunderstands the role and significance of patenting. The grant of a patent, it is rightly observed, is not normally regarded as giving permission or positive authority to exploit the invention, nor is it "an expression of approval or disapproval."¹⁵⁸ In fact, the opposite is true: patented inventions are subject to general

¹⁵⁰ Biotech. Dir., Art. 6(2)(a)). Recital 41 elaborates further 'any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being.' The provision is implemented at the European Patent Office under EPC Rule 28(a).

¹⁵¹ Biotech. Dir., Art. 6(2)(b). Implemented by EPC Rule 28(b).

¹⁵² EPC Rule 28(c). For interpretation, see especially *G_2/06 WARF Stem Cells* [2009] EPOR (15) 129 (Enlarged Board of Appeal, 25 November 2008) holding claim unpatentable if, at the filing date, the only way in which the claim could be given effect involved the destruction of embryos).

¹⁵³ Biotech. Dir., Art. 6(2)(d); EPC Rule 23d(d). The provision was applied in T315/03 *Oncomouse* esp. paras 9.1-9.7, 12.2 (as regards claim to 'rodents' – squirrels, beavers and porcupines - no benefit), 13.2 (when confined to 'mice' passed test)

¹⁵⁴ 447 US 303, 309, 317 (1980) (US S Ct).

¹⁵⁵ Jennifer McCallum, 'The Reality of Restricting Rights on Morally Controversial Subject Matter,' (2005) 39 New Eng L R 517, 517-8 (emphasis in original).

¹⁵⁶ Margo Bagley, 'Stem Cells, Cloning and Patents: What's Morality Got to Do with It?' (2005) 39 New Eng L R 501, 506.

¹⁵⁷ *Commissioner of Patents v. President and Fellows of Harvard College* [2002] 4 S.C.R. 45 (S. Ct. Can) (para 11) (Binnie J.). Indeed, as Binnie J. explains at para 14, the Canadian Parliament repealed a provision contained in s. 27(3) of the Patents Act against patenting an "invention that has an illicit object in view."

¹⁵⁸ *Commissioner of Patents v. President and Fellows of Harvard College* [2002] 4 S.C.R. 45 (S. Ct. Can) (Binnie J., dissenting) (para. 14).

law and regulation.¹⁵⁹ To permit patenting of firearms, for example, does not mean that firearms can be bought or sold otherwise than in accordance with the general law (for example, requiring a licence). To permit patenting of genetically-modified organisms would not prevent anyone carrying out experiments with such organisms from complying with relevant regulatory controls (designed to protect, for example, the well-being of the animal or the integrity of the environment). There is a “fundamental distinction ...between patentability of an invention and regulation of an activity associated with an invention.”¹⁶⁰

(vi). Exclusions that recognise countervailing policy considerations.

The final category of exclusions are informed by goals outside of patent law that mean that patenting is regarded as inappropriate. Traditional exclusions – no longer permitted under TRIPs art 27– of “medicines” and “food” from being patented may be regarded as having been justified on this basis. Maximising access to food and medicine are such fundamental social goals that the means of their production should, it might be said, never be permitted to fall into private, monopolistic, control. Some countries do, however, maintain the possibility of operating such exclusion. The Patent law of Ghana, for example, excludes “products and processes excluded by law for national security, economy, health or any other national concern,” while Jordan and Moldova exclude from protection inventions necessary to protect the life and health of humans. Kenya similarly excludes “designated methods for the prevention or treatment of serious health hazards and life threatening diseases.” These systems recognise that in certain circumstances, where the free exploitation of an invention is necessary to promote public health (etc), there should be no property rights over those subjects. The logic of patent law should give way to the greater social good.

Health and food security are not the only fundamental freedoms that might conflict with patent law. Commentators have identified other countervailing freedoms such as free speech, privacy that might also be relevant.¹⁶¹ Indeed, Thomas Cotter has argued that at least some of the recognised exclusions from patentability under US law may well be explicable by reference to such interests. Patents on “laws of nature”, he argues, “would also lead to administrative difficulties and would intrude upon personal autonomy in troubling ways.”¹⁶²

¹⁵⁹ In many federal countries, this distinction is not merely one of principle but has constitutional weight: patent laws falling within the federal power and criminal law within local state jurisdiction. See e.g. *Webber v. Virginia*, 103 US (13 Otto) 344, 347-8 (US S Ct, 1880) (“Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted.”)

¹⁶⁰ *Commissioner of Patents v. President and Fellows of Harvard College* [2002] 4 S.C.R. 45 (S. Ct. Can) (Binnie J., dissenting) (para. 15); *Juicy Whip Inc v Orange Bang Inc*, 185 F.3d 1364, 1368 (Fed. Cir. 1999) (no objection to patenting inherently deceptive device, noting that other agencies protect consumers from deception); Jennifer McCallum, ‘The Reality of Restricting Rights on Morally Controversial Subject Matter,’ (2005) 39 New Eng L R 517, 519.

¹⁶¹ Thomas Cotter. ‘A Burkean Perspective on Patent Eligibility, Part II: Reflections on the (Counter) Revolution in Patent Law (2010) 11(1) Minn. J. L. Sci & Tech 365, 377 (proposing an exclusion from patent eligibility of inventions where their “enforcement would unduly interfere with fundamental liberty interests”).

¹⁶² Thomas Cotter. ‘A Burkean Perspective on Patent Eligibility’. 22 Berk Tech LJ 855 (2007)

E. RATIONALES FOR EXCEPTIONS AND LIMITATIONS OF THE RIGHTS

Very little thought has really been offered hitherto to the rationales for exceptions to patentee's rights. Often legislators have simply done what they intuitively sensed was fair or sensible, or forged compromises between different lobbying interests. Rarely has there been offered a careful analysis of when and why limits are drawn where they are, or how incommensurable values are to be weighed against one another. That said, we think the rationales for exceptions to patentees rights tend to fall within three general categories: (i) those that reflect patent law's cost-benefit analysis; (ii) those concerned with facilitating the functioning of patent law; and (iii) those that reconcile conflicts between the patent monopoly and other social goals or values (including perhaps fundamental rights).

(i) Exceptions that Reflect Patent Law's Cost-Benefit Analysis

Some exceptions from a patentee's rights can be explained by reference to the core rationale for the provision of patents: to incentivise investment in research and the disclosure of information by the provision of short term monopoly rights. In principle, patents should only be granted where, *and to the extent that*, such monopolies are required to rectify market failure. And they should not be granted where to do so will in fact restrict further invention. The latter calibration is sometimes referred to as an exercise in "balancing", or the "incentives-access paradigm". Essentially, there is a cost-benefit analysis: can the same incentive effect be provided with less social cost? Or, would a marginal reduction in the incentive lead to a significant reduction in social cost?

Some limitation on patentee's rights can be explained by the fact that extending protection to cover the permitted act would not enhance incentives significantly (or appropriately). This is a common explanation for exceptions relating to private use (or the corollary, the limitation of the patentee's rights to commercial, trade or business uses.) Many countries exclude from liability either *de minimis* uses,¹⁶³ or uses that are non-commercial. The Egyptian law permits "Acts not prejudicial to normal exploitation of the patent, or the interests of patent owner and third parties." The Community Patent Convention – which never came into operation but influenced the drafting of the laws of many European countries - provides that acts that are done privately *and* for non-commercial purposes do not infringe.¹⁶⁴ In the United Kingdom this has been interpreted as meaning that while private uses need not be secret or confidential, they must be 'for the person's own use'.¹⁶⁵ Where an activity has both commercial and non-commercial benefits, it is necessary to ascertain the subjective intention of the user. If the infringer was motivated by commercial interests, the defence would not apply. However, if the subjective purposes were non-commercial, the defendant could rely on the immunity. This is the case even if the resulting information has a commercial benefit.¹⁶⁶

¹⁶³ See e.g. *Finney v. United States* 188 USPQ 33 (CCTD 1975). The experimental use exception was sometimes viewed as part of the *de minimis* rule: *Byam v. Bullard*, 4 F. Cas 934, 935 (CCD Mass 1852) (No 2262).

¹⁶⁴ CPC Art. 31.

¹⁶⁵ *SKF Laboratories v. Evans Medical* [1989] FSR 513, 518; *McDonald v. Graham* [1994] RPC 407.

¹⁶⁶ *SKF Laboratories v. Evans Medical* [1989] FSR 513.

Private or non-commercial uses can, in general, be thought of as uses which are unlikely to add much, if anything, to the “incentive” provided by the patent monopoly. At the same time, allowing patents to cover such activities would impose significant costs: most obviously, there would be the transactions costs of policing and licensing such uses. In the field of copyright, it became common in the 1980s to explain the US doctrine of “fair use” (and non-US equivalents such as “private copying” exceptions) as the legal response to what economists call market failure – circumstances where in a world without transaction costs, parties might agree to particular sorts of use, but where the existence of those transaction costs prevents such agreement.¹⁶⁷ The same sort of explanation, whether put in the language of market failure or in terms of cost-benefit analysis, appears to inform “private use” exceptions to patentee’s rights. Some narrow forms of the “experimental use” exception might also be justified on this basis. The Indonesia version of this exception, for example, predicates the application of the exception on an absence of prejudice to the patentee.¹⁶⁸

The “calibration” or “balancing” dimension also is used to explain exceptions from research and scientific purposes.¹⁶⁹ Here the argument is that even if the uses were public and commercial, uses for research and science are directed to producing new inventions or technology.¹⁷⁰ If the overall social goal is to maximise invention, then this is one area where patent laws should be limited: otherwise patent laws would end up restricting precisely the sorts of activity that they are intended to maximise. As Professor Katherine Strandburg explains:

“The purpose of an experimental-use exemption should be to protect the patentee’s ability to recoup her research and development investment while preventing her from using her exclusive rights to exercise unwarranted control over subsequent innovation.”¹⁷¹

“Research tools” occupy a peculiar position within this calibration. This is because allowing third parties to use research tools without payment under a “research” exception would likely undermine completely any incentive to invest in the creation of the research tools themselves. It is for this reason that many legal systems seek to limit the operation of the research exemption to cover uses “on” the invention rather than “with” the invention.

¹⁶⁷ The classic exposition is Wendy Gordon’s: W. Gordon, ‘Fair Use as Market Failure’ (1982) *Columbia LR* 1600.

¹⁶⁸ Indonesia (“Use for purposes of education, research, experiment or analysis not prejudicial to the patent owner.”)

¹⁶⁹ O’Rourke at 1198 (Now is the time to “adopt a doctrine of fair use that brings the balance between exclusive rights and the public welfare that implicitly informs conventional doctrine into the ope.”)

¹⁷⁰ Henrik Holzapfel & Joshua D. Sarnoff, *A Cross-Atlantic Dialog on Experimental Use and Research Tools*, 48 *IDEA* 123 (2008) (“Some of the arguments for a broader exception rest upon the rationale of promoting technological progress...”).

¹⁷¹ Katherine Strandburg, ‘What Does the Public Get? Experimental Use and the Patent Bargain,’ (2004) *Wis L Rev* 81,100.

According to some, the notoriously narrow experimental use defence operating in the US has not caused significant difficulties (yet).¹⁷² Yet there is widespread dissatisfaction amongst academics, at least, with the current state of US law. Ever since Professor Eisenberg published her ground-breaking article on the topic in 1989,¹⁷³ one scholar after another have stepped up to propose some sort of reform to provide the defence with greater flexibility.¹⁷⁴ In 2000, Professor Maureen O'Rourke, proposed the adoption of a "fair use" exception to patent infringement. Three years later, Professor Rochelle Dreyfuss, perhaps inspired by the viral licences utilised in the GPL and by Creative Commons, proposed that public institutions are able to use patented inventions in experiment so long as they undertake that any products of such research are themselves placed into the public domain.¹⁷⁵ The following year, Richard Nelson proposed a similar scheme, instead conditioning the exception for the non-profit institution on an undertaking to license on a non-exclusive basis and for a reasonable royalty any patented outcome of the research.¹⁷⁶ Professor Katherine Strandburg has proposed a combination of an exception for "experimenting on" (such as that which operates in Germany and the United Kingdom) with a compulsory licence for "experimenting with" a patented invention.

The "Bolar" exemption brings in another dimension to the cost-benefit analysis: that of consistency between fields of technology. Compare two fields of technology: mechanical inventions and pharmaceuticals. In the former case, as soon as the patent lapses, a competitor can market the product. In the latter, absent a Bolar provision (or broad conception of experiment that includes satisfying third party agencies), the product cannot be marketed once the patent lapses. Rather, it is only then that the competitor can begin to satisfy the regulatory authorities. In effect, then, in the latter field the patentee obtains a longer monopoly. On the assumption that the legislature correctly calculated the optimal patent term, the effect is to confer an unnecessarily lengthy monopoly period on the pharmaceutical patentee. A Bolar exemption, allowing experiment during the patent term to satisfy regulatory authorities, in principle, places patentees back on an equal footing and ensures that the pharmaceutical patentee does not receive more than optimal protection. (In practice, of course, many countries have also conferred extended terms on patentees who have lost periods of exclusivity because of time involved in them gaining regulatory approval).

¹⁷² The literature is reviewed by Michael Carrier, *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law* (OUP, 2009) Ch 11 ('Biotechnology Dilemma 1: Patented Research Tools and Experimental Use').

¹⁷³ Rebecca Eisenberg, 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' 56 U. Chi. L. Rev 1017 (1989).

¹⁷⁴ Note also: Donna Gitter, International Conflicts over Patenting DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair Use Exemption (2001) 76 NYULR 1623; Janice Mueller, No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools (2001) 76 Wash LR 1.

¹⁷⁵ Rochelle Dreyfuss, Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course in F. Scott Kieff (ed) *Perspectives on Properties of the Human Genome Project* (2003).

¹⁷⁶ Richard Nelson, The Market Economy and the Scientific Commons, (2004) 33 Research Policy 455.

(ii) Exceptions Necessary to the Patent System

The second type of exception can be dealt with quickly. This is the category of exceptions that are needed to maintain the functioning of the patent system itself. The most obvious of these is the “experimental use” exception. As it is a universal premise of modern patent systems that the patentee disclose the invention to the public so that they can perform the invention, it is clearly necessary that persons can experiment with the invention to ascertaining whether it in fact works (and is sufficiently disclosed). As patent offices do not undertake this task, this freedom must be conferred on competitors, as it is they who have the incentive to investigate and ultimately challenge the validity of the patent. Moreover, this capacity to investigate the invention must be given from the moment the patent is granted. After all, there would be no point in requiring these competitors to wait until after the patent had lapsed before they could challenge the patent.

This justification for the experimental use exception would, of course, justify only a narrow exception to experiment “on the subject matter” of the invention. It would, however, be completely compatible with experiments which ultimately have a commercial purpose. After all, the competitor’s motivation is to compete.

(iii) Exceptions which Reflect Countervailing Individual and Public Interests

Other exceptions reflect the fact that incentivising innovation, while a important social goal, is sometime in conflict with other social goals or private interests, and the latter are regarded as of a higher rank or importance. The most obvious examples here are the exceptions and compulsory licence relating to national security and emergencies, such as the exception in the Bangui Accord that permits exploitation by an administration or organization authorized by the Minister of the Member State concerned, for the purposes of “vital economic interest, public health, defence or the country's needs”, subject to remuneration.¹⁷⁷

Other countervailing public interests include free competition, education and privacy. We have already referred to specific exceptions that are made available in some countries laws to remedy anti-competitive practices, though in many countries the competition law norms themselves might be found to constitute a defence (or will give the relevant authorities and/or courts remedial flexibility that would include the grant of compulsory licences). Education seems to be prioritised over patentees’ interests, in the countries (mostly from Central South America) which expressly except use in teaching from the patentee’s rights.¹⁷⁸ Arguably, privacy interests also justify the exception for “private use” (though, as we have already noted, this exception can also be justified on the basis of “market failure”.)

Exceptions may also operate to reconcile patents with private interests. One such interest is the “right of property” in tangible objects (and the social interest in the

¹⁷⁷ Ukraine (Use in emergency conditions (natural disaster, accident, epidemic etc; use, by a person authorized by the Cabinet of Ministers, to protect the health of population, ecological safety or other public interests); Uzbekistan (use in cases of natural calamities, disasters, epidemics and other exceptional circumstances).

¹⁷⁸ Argentina, Bolivia, Columbia, Costa Rica, Ecuador, Guatemala, Mexico, Nicaragua, Peru, and Uruguay. The two other countries are Poland and Switzerland.

alienability of such property). The conflict between the scope of intellectual property rights and property rights can be seen most obviously in the doctrine of “first sale” or “exhaustion of rights”. Here, the presumption in the free alienability of tangible property prevents patentee’s rights reaching beyond the first marketing of patent products.¹⁷⁹ In Europe, the principle of exhaustion of rights also represents a prioritisation of the goal of creating a single Community.

Sometimes, exceptions may also be regarded as desirable in order to maintain existing social practices and expectations. One obvious example relates to the farmers’ privileges, described particularly in chapter 3 by Professor Barbosa. But the preservation of expectations may also provide the most convincing rationale for the US exception for use of certain methods by medical practitioners.

F. EXCLUSION AND EXCEPTIONS: WHAT IS AT STAKE?

Our survey suggests that not all concerns that drive exclusions can be adequately accommodated within exceptions. This is because the exclusions are motivated by other rationales. In particular, we have identified:

- (a) exclusions that clarify what is understood by the term “invention”;
- (b) exclusions that give-effect to policies from other areas of patent law with a “bright-line” rule;
- (c) exclusions that reflect the fact that protection is afforded elsewhere (under copyright or plant breeders rights) and seek to mark the boundaries between the different regimes.
- (d) exclusions that exist because no legal incentive is required (for example because the invention is motivated by self-interest or by reputational norms)¹⁸⁰
- (e) exclusions in relation to inventions that are positively undesirable
- (f) exclusions that recognise countervailing policy considerations.

It is possible to utilise exceptions rather than exclusions to accommodate a number of these goals.

Most obviously, exceptions can be utilised to massage the “cost-benefit” analysis that informs the exclusion from patentability of some matter: the use of an exclusion might exclude some “costs” or maximise some “benefits” (such as follow on innovation), thus making the overall utility calculation favour patentability (rather than an exclusion). That said, an exception might be justified just to improve such cost-benefit analysis, even if patentability is favoured.

¹⁷⁹ Alternatively, “exhaustion” might be said to be justified through a cost-benefit analysis. Absent a first sale doctrine considerable social costs would have to be incurred by potential purchasers of tangible properties, but it is not obvious that these costs would lead to a significant increase in the patentee’s returns. The necessary incentive is probably sufficiently provided by the right to extract a monopoly price from first sale of artefacts.

¹⁸⁰ Strandberg has developed an interesting distinction between “user” and “seller” inventions: (2008) 79 U Colo LR

Similarly, exceptions may play an important role in easing the discontinuities between different legal regimes, and thus make overlapping regimes less unattractive. Thus, it might be that, in so far as the exclusion of “plant varieties” and “computer programs” is because these subjects fall within other, carefully tailored regimes, one possibility is to allow patenting but to incorporate some of the “tailoring” by way of exceptions. Indeed, the increasing use of “farmers’ exceptions” in patent regimes largely reflects the importation of the exception from plant breeders’ rights laws. The draft proposed Community patent likewise would incorporate inter-operability exceptions for software from the 1991 Directive dealing with copyright protection of computer programs.

Advantages and Disadvantages of Exclusions and Exceptions.

The chief advantage of an exclusion over an exception is its potential for clarity and certainty. Its chief disadvantage is its bluntness: it removes all the incentive (rather than balancing it or reducing it) and may drive operators to using alternative forms of protection. The chief advantage of exceptions is that they can be carefully tailored and subject to conditions. The main disadvantage is that they may prompt judicial expansion of patentee’s rights and may not leave users with much certainty. However, as the supposed clarity that “exclusions” provide often turns out to be illusory, we think there is much to be said for more widespread use of exceptions as policy levers.

(i) The Clarity of Exclusions

Perhaps the most obvious advantage with an exclusion for the scope of subject matter is the certainty it can afford users. In *Festo Corp v Shoketsu Kinzoku Kogyo Kabushiki Co* (2002), the Supreme Court of the United States emphasised the importance of clear boundaries for monopoly rights:

“The monopoly is a property right; and like any property right, its boundaries should be clear.”

Similarly, in *Brenner v Manson* the Supreme Court justified the “utility” requirement by reference to its role in the “precise delineation” of the “metes and bounds” of the patentee’s monopoly.

In *Bilksi*, Stevens J. reiterated that “[I]n the area of patents, it is especially important that the law remain stable and clear.”

The public simply does not have to concern itself with whether any inventions have been registered, their validity, the scope of rights (in particular whether their action falls within the scope of claims) or the precise limits of any exceptions. If the activity or product that a person wishes to deal with falls within an exclusion, that person simply does not need to concern themselves with the patent system. So, all scientists know that they can develop products or systems or processes that rely on particular scientific principles, without needing to worry about whether those principles are patented. Likewise, doctors in Europe can be confident that they can use certain medical techniques (whether or surgery or therapy or diagnosis), without worrying about patents.

In 2003, the UK's premier scientific society, the Royal Society stated:¹⁸¹

“It is of particular importance to the scientific community that modifications to these exclusions from patentability do not lead to a greater risk of scientific knowledge being monopolised. We agree with the view of many scientists that pure knowledge about the physical world should not be patentable under any circumstances. That it should be freely available to all is one of the fundamental principles of the culture of science. Only by having knowledge unencumbered by property rights can the scientific community disseminate information and take science forward.”

This sentiment explains why various lobbyists and interest groups call for the per se exclusion of the patentability of genes: because they want it to be absolutely clear that scientists can utilise genes in various ways without worrying about the complexities of patent law.¹⁸² Although some have denied that patenting inhibits the free flow of knowledge in the way that these critics suggest (for example, emphasising the existence of research exemptions),¹⁸³ what is of interest here is not the merits of the specific positions, so much as the legal expression of the policy as an exclusion from patentability.

(ii) The Bluntness of Exclusions

The chief disadvantage for policy-makers with deploying exclusions is their bluntness. Four members of the Supreme Court of Canada, dissenting against the decision that higher life forms are unpatentable subject matter, expressed its concerns:

“[T]he grant of a patent simply reflects the public interest in promoting the disclosure of advancements in learning by rewarding human ingenuity. Innovation is said to be the lifeblood of a modern economy. We neglect rewarding it at our peril.”¹⁸⁴

U.S. Professor John Duffy has made a similar point. There is, he says “an important asymmetry ...in the costs of a rule *restricting* patentable subject matter as opposed to the costs of a rule *expanding* patentable subject matter.”¹⁸⁵ This is because an over-expansive subject matter can be mitigated by altered rules on inventive step, disclosure, sufficiency, infringement or exceptions. However, an overly-restrictive rule removes any incentive altogether, and there is no way the system can mitigate for that. Likewise, Thomas Cotter observes “patent eligibility is a crude filter for carrying

¹⁸¹ Royal Society, *Keeping Science Open* (London, 2003) para. 3.5.

¹⁸² Joseph Stiglitz & John Sulston, ‘The Case Against Gene Patents,’ *The Wall St Journal* (April 16, 2010); ‘Human Genome Project Leader Warns Against Attempts to Patent Genes,’ *The Guardian*, June 24, 2010 (reporting John Sulston’s speech on the 10th anniversary of the first draft of the human genome project). See also Sulston & Sarah Chan, ‘Patents in Synthetic Biology May Hinder Future Research,’ (2010) *British Medical Journal* 340.

¹⁸³ See e.g. CIPA President Alasdair Poore’s comments at <http://www.cipa.org.uk/pages/press/article?D5C2CBED-894B-488B-ACD2-07B01E204A06>

¹⁸⁴ *Commissioner of Patents v. President and Fellows of Harvard College* [2002] 4 S.C.R. 45 (S. Ct. Can) (para 4) (Binnie J.)

¹⁸⁵ John F. Duffy, ‘Rules and standards on the Forefront of Patentability,’ (209-10) 51 *Wm & Mary L. Rev.* 609, 622-3.

out social policy” and thus should be “reserved for the relatively ‘easy’ cases.”¹⁸⁶ Outside those ‘easy cases’, Cotter argues that other policies are better effected “by other patent law doctrines”, (though he suggests non-obviousness, claim definiteness, and enablement doctrine.)

One consequence of the bluntness of such exceptions is that they become prone to obsolescence. In an insightful discussion of whether patentability should be characterised by reference to “rules” or “standards”, Professor John Duffy explains how, when presented as rules, patent-eligibility requirements demonstrate a tendency to become rapidly out-dated. Although his examples come largely from US history, and to a small extent recent European experience, he argues that

“[t]he failure of patent eligibility rules appears to be a general phenomenon spanning time and geography.”¹⁸⁷

In part, this is attributable to the inherent unpredictability of what will, in the future, present itself at the patent office doors, but also, he argues to the “intractability of the ultimate policy issues” which depend on balancing empirical data which is rarely (if ever) before the court.¹⁸⁸ These factors lead courts to develop ways round exclusions, expanding the domain of patentable subject matter.

Rochelle Cooper Dreyfuss makes a similar point, when proposing that the US law consider an expansion of its experimental use defence rather than a limitation on patentability.¹⁸⁹ Dreyfuss argues that historically speaking much research activity has been able to occur in an environment free from concern with issues of patents, but that this has changed for a number of reasons. One reason is that the exclusions from patentability of “principles of nature as in *Morse*, features of nature as in *Funk*, and research tools, as in *Brenner*” no longer facilitate scientific research in the same way as they once did.¹⁹⁰ For Dreyfuss, this is as much attributable to the “characteristics of modern science” as much as with judicial expansionism or Patent Office laxity. Taking the example of biotechnology, Dreyfuss observes that the distance between basic research and commercial application is often perceived to be very narrow (perhaps even non-existent): inventions in genomics and proteomics have immediate applications, but also remain of critical significance for researchers. Dreyfuss argues that the optimal response is not to rewrite the exclusions from patentability, but to develop exceptions. Changing the law of patentability

“will not change the dual character of the fruits of modern science...The carve-outs that are made may provide too little incentive to the end-use dimension of the subject matter excluded, leading to under-dissemination and utilization. Furthermore, it would be difficult to decide whether a field needs to be excluded until after inventions in the field emerge.”¹⁹¹

¹⁸⁶ Thomas Cotter. ‘A Burkean Perspective on Patent Eligibility, Part II: Reflections on the (Counter) Revolution in Patent Law (2010) 11(1) *Minn. J. L. Sci & Tech* 365, 379.

¹⁸⁷ John F. Duffy, ‘Rules and standards on the Forefront of Patentability,’ (209-10) 51 *Wm & Mary L. Rev.* 609, 638.

¹⁸⁸ *Ibid.*, 618-9.

¹⁸⁹ Rochelle Dreyfuss, ‘Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?’ (2004) 46 *Ariz L R* 456.

¹⁹⁰ *Ibid.* 462.

¹⁹¹ *Ibid.* 468.

(iii) The Negative Effects of Exclusions

Dreyfuss's comments highlight a further problem with denying patentability (rather than extending exceptions): removal of subject matter from the fields of patentability altogether means that the patentee (and society) loses all the benefits of a patent property right. These might include the advantages of patents as signals,¹⁹² as incentives to exploit,¹⁹³ and as tools for the co-ordination of research activities (for example, linking basic research to clinical trial).¹⁹⁴ Although few commentators would regard such benefits as, of themselves, sufficient to justify the social costs of a patent system in general, they are matters that might be regarded as relevant where the arguments over whether to exclude subject matter or not are finely balanced.

Another objection is that a finding of unpatentability encourages secrecy. The exclusion of particular fields from patentability will inevitably prompt those operating in these fields to look for alternative mechanisms of protection. Empirical work in the US suggests that the use of trade secrets is already a preferred form of "appropriability mechanism" for many businesses. Where the nature of the invention would not be apparent from the marketed product (as for example, where the invention is a better or cheaper process for making a known product) trade secrecy is regarded as a particularly attractive form of protection. From a social perspective, there is a long-standing fear that the use of such mechanisms might ultimately deprive society of the invention (as, for example, where the secret "dies" with its inventor.

The US Supreme Court considered such an objection to its refusal to patent a method of producing a known substance where the substance itself lacked value in *Brenner v. Manson* in 1966. It stated:

"It is true, of course, that one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions. And it may be that the inability to patent a process to some extent discourages disclosure and leads to greater secrecy than would otherwise be the case. The inventor of the process, or the corporate organisation by which he is employed, has some incentive to keep the invention secret while uses for the product are searched out. However, in light of the highly developed art of drafting patent claims so that the disclose as little useful information as possible - the argument based upon the virtue of disclosure must be warily evaluated. Moreover, the pressure for secrecy is easily exaggerated, for if the inventor of a process cannot himself ascertain a 'use' for that which his process yields, he has every incentive to make hid invention know to those able to do so..."

¹⁹² Clarissa Long, 'Patent Signals,' (2002) 69 U Chi L R.

¹⁹³ Edmund Kitch, 'The Nature and Function of the Patent System,' (1977) Jo L & Econ 265 ("prospect theory"; and Scott Kieff, 'Property Rights and Property Rules for Commercializing Inventions,' (2001) 85 Minn L R 697.

¹⁹⁴ Paul Heald, 'A Transaction Cost Theory of Patents' on SSRN.

(iv) The Advantages of Exceptions

If exclusions suffer from “bluntness” (and potential negative side-effects), exceptions correspondingly can be more finely tuned to ensure that an appropriate compromise is made within the patent system. As Professor Duffy suggests, in his study of exclusions from patentability, “alternatives may be better able to address any underlying policy concerns.”¹⁹⁵ It is easy to see that an exclusion, if effective, operates like an “on/off” switch, whereas exceptions are more like “dimmer switches”, than can be turned down (to reduce costs), without necessarily turning off the light. The prior use defence, the experimental use defence, the private use defence, exhaustion of rights reduce incentives, they do not remove them altogether. Exceptions can be conditioned, for example by requiring some remuneration, and this highlights the much more nuanced way in which they might operate to reconcile conflicting interests.

Other advantages for exceptions derive from the position that they occupy within the patent system. Because exclusions are scrutinised particularly during the granting process, they are increasingly the subject of international and regional standardisation as attempts are made to reduce the cost of patenting, whether by way of international application and examination systems (such as the PCT) or regional grant systems. As other mechanisms of co-operation develop, such as outsourcing search and examination, it seems likely that further pressures will exist to remove or limit exclusions. In contrast, exceptions remain largely unstandardised (except for TRIPs) and there seems less reason for promoting further standardisation.

Exceptions also offer the advantage that they are administered primarily by the courts, whereas exclusions tend to be administered in the first instance by offices. Patent offices often have tendencies when in doubt to grant patents, while courts rarely seem to feel the same pressures. Thus exceptions are much more likely to end up as significant limitations, whereas the public interests of exclusions may very well become overlooked in the negotiations between a Patent Office and its “customers” during the prosecution of applications. Relatedly, while an exclusion can be circumvented through clever claim-drafting, exceptions are less susceptible to such techniques.

Finally, exceptions could also offer considerable residual flexibility. Exclusions from patentability tend to operate by way of categories devised *ex ante*.¹⁹⁶ In contrast, it would be possible to operate with a residual flexibility in relation to exceptions (as, for example, with the US fair use doctrine in copyright). A possible example is the provision within the law of Argentina that permits “exploitation by a third party allowed by the Office without the authority of patent owner, subject to remuneration.”

¹⁹⁵ John F. Duffy, ‘Rules and standards on the Forefront of Patentability,’ (2009-10) 51 *Wm & Mary L. Rev.* 609, 637.

¹⁹⁶ That said, at least in Article 52 of the European Patent Convention the exclusions are a non-exhaustive list. Other “non-inventions” would not be patentable in principle.

(v) The Dangers of Exceptions

One danger with utilising exceptions is that, in some jurisdictions at least, the existence of an exception from patentability may be taken to indicate that the very same subject matter must be patentable. In other words, an exception to a patentee's rights can become a source for interpreting the scope of subject matter. Exactly this happened in the decision of the majority of the U.S. Supreme Court in the decision in *Bilski v Kappos*¹⁹⁷. Whereas the minority was prepared to find a "business methods" exclusion from patentability,¹⁹⁸ the majority held that no such exclusion existed: some methods of business would be excluded from patentability as "abstract processes" (as with the subject matter in issue, a procedure for instructing buyers and sellers how to protect against the risk of price fluctuations), but if an application did not relate to subject matter within the three traditional exclusions (namely, "laws of nature, physical phenomena, and abstract ideas") it was prima facie patentable.¹⁹⁹ In rejecting the suggested business methods exclusion, the majority was influenced by the fact that Congress had passed the "prior user" exception in section 273(a)(3). According to this, if a patentee claims infringement on the grounds that that defendant has used "a method of doing or conducting business" covered by the patent, the defendant is able to assert a defence of prior use. This indicated that Congress regarded some business methods as patentable. As Justice Kennedy explained:

" [W]hat s. 273 does is clarify the understanding that a business method is simply one kind of 'method' that is, at least in some circumstances, eligible for patenting under s.101...A conclusion that business methods are not patentable in any circumstances would render s. 273 meaningless."

In contrast, the minority (led by Justice Stephens) considered this to be an inappropriate inference to draw from the addition of the exception to the statute book. The First Inventor Defense Act of 1999 was "a stopgap measure designed to limit a potentially significant new problem for the business community," that arose as a result of the Federal Circuit decision in *State Street Bank*.²⁰⁰ Inferring from that Act the conclusion that Congress intended business method to be patentable involved a "flawed method of statutory interpretation" and ignored "the motivation for the 1999 Act."²⁰¹ The passage of the Act reflected "surprise and perhaps dismay" at the conclusion in *State Street*, as opposed to approval of the extension of patentability. As Justice Stevens explained

"The fact that Congress decided it was appropriate to create a new defense to claims that business method patents were being infringed merely demonstrates recognition that such claims could create a significant new problem for the business community."

¹⁹⁷ *Bilski v Kappos* 561 US __ (2010).

¹⁹⁸ Stevens J ("More precisely, although a process is not patent-ineligible simply because it is useful for conducting business, a claim that merely describes a method of doing business does not qualify as a 'process' under s. 101.")

¹⁹⁹ *Diamond v Chkrabarty* 447 US 303, 309 (1980)

²⁰⁰ 149 F. 3d 1368.

²⁰¹ Stevens at [34].

(vi) The Illusion of Clarity of Exclusions

The reality is, of course, that exclusions from patentability are a constant source of contention. As the US Supreme Court observed in *Parker v Flook* (1978), [t]he line between a patentable process and an unpatentable principle “does not always shimmer with clarity,”²⁰² while Justice Breyer has acknowledged “that the category of non-patentable ‘phenomena of nature,’ like the categories of ‘mental processes’ and ‘abstract intellectual concepts,’ is not easy to define.”²⁰³

Patentees, advised by skilful patent agents, constantly test the scope of any exclusion, cleverly drafting claims in a manner that deviates from the subject of the exclusion or abstracting away from the subject matter in a way that disguises its nature. Thus, for example, a patentee who has invented a method of treatment may attempt to patent it by drafting a broader claim to a product or system, or even a claim to a “use” of a particular substance in treating a specified disease. Similarly, an inventor of an animal variety might be inclined to assume that the invention applies to a range of animals and claim at a higher taxonomical level.²⁰⁴ Equally, the inventor of a computer program may seek to protect it indirectly via a claim to “a computer when loaded with the program”. Alternatively, faced with an exclusion of “abstract principles” an applicant might seek to avoid the exclusion by confining the application to a particular field, or adding token post-solution components.²⁰⁵ As a consequence, John Allison & Emerson Tiller,²⁰⁶ argue against ex ante exclusions:

“Treating different technologies differently places too great a premium on ex ante definitions, such that the definitional scheme will be at least partially defeated because of the significant transaction costs associated with attorney efforts to opt into or out of a definition by carefully tailoring inventions descriptions and patent claims.”

But the determination of patentable subject matter cannot just depend on “the draftsman’s art”²⁰⁷ In response, patent offices and courts are constantly called upon to see through claim language and to identify what the subject of the invention really is.²⁰⁸ But the mechanisms and approaches to so doing may vary, even within a single legal system, depending (amongst other things) on the perceived need to keep excluded subject matter free. Sometimes subject matter may be unpatentable if it

²⁰² *Parker, Acting Commissioner of Patents and Trademarks v Flook*, 437 US 584, 589 (1978, US S Ct) (Justice Stevens).

²⁰³ *Lab Corp of America v Metabolite Labs., Inc*, 548 US 124, 134 (U.S. S. Ct, Breyer J. (dissenting), 2006).

²⁰⁴ Note also *Commissioner of Patents v. President and Fellows of Harvard College* [2002] 4 S.C.R. 45 (S. Ct. Can) (even though genetically modified animal is unpatentable “fertilized, genetically altered ...egg is an invention” under Canadian patent law).

²⁰⁵ *Parker, Acting Commissioner of Patents and Trademarks v Flook*, 437 US 584, 589-90 (1978) (application limited to petrochemical and oil-refining industries. Held: this could not save what was otherwise to be regarded as unpatentable algorithm.)

²⁰⁶ ‘The Business Method Patents Myth,’ 18 Berk Tech LJ 987, 1021 (2003). The comment is made also in the context of exceptions to rights.

²⁰⁷ *Parker, Acting Commissioner of Patents and Trademarks v Flook*, 437 US 584, 589 (1978, US S Ct) (Justice Stevens).

²⁰⁸ *Parker, Acting Commissioner of Patents and Trademarks v Flook*, 437 US 584, 590 (1978, US S Ct) (Justice Stevens) (“The concept of patentable subject matter... is not like a nose of wax which may be turned and twisted in any direction...”).

includes any matters within a prohibited field, while in other cases the tribunals and offices are more facilitative, only refusing to patent claims that go no further than excluded subject matter (as, in particular, with “as such” exceptions). Sometimes offices and examiners treat the excluded matter as if it were part of the public domain, requiring novelty and inventiveness to be located elsewhere within the claimed subject matter;²⁰⁹ on other occasions, the examiners examine the claims “as a whole”, so that the excluded matter can contribute to the novelty and inventiveness of the whole.²¹⁰ Even where the case-law suggests that patentability should be judged by looking at the claimed invention “as a whole”,²¹¹ doctrines seem inevitably to emerge giving the examiner leeway to characterise the “essence” or “substance” of the invention or “solution” and to exclude other peripheral or “post-solution” components.²¹²

Whatever mechanism is deployed to determine whether a particular claim which is not literally directed at excluded subject matter should nevertheless be regarded as unpatentable, a further issue that arises is the willingness of patent offices to determine these issues *ex ante*, that is prior to grant. Here we see at least two common problems. First, to the extent that an exclusion from patentability requires a patent office to make some sort of prediction as to how the subject matter of the invention might be used or deployed, it is inevitably difficult for the office to apply the exclusion. This is particularly so in relation to exclusions of “immoral” inventions (though here patent offices also often feel that they lack the competence to apply the exclusion). Secondly, and more importantly, there is an issue about the best use of limited patent office resources. Should patent offices accept applications relating to unpatentable subject matter, and consequent application fees, leaving it to competitors to remove the invalid patents from the register through revocation proceedings? If not, should the patent office only refuse obviously unpatentable subject matter, allowing registration of claims that appear on their face to be plausible? If some serious investigation is to be undertaken, how much effort and resource should be put into investigating subject matter issues? Moreover, is that effort best applied when substantive inventiveness is investigated, or as a preliminary matter? The answers to the questions are not obvious.²¹³ Different patent systems will answer these questions in their own way, reflecting, most obviously, whether they see their role as protecting the public and maintaining a register that comprises, as far as possible, only valid patents; or as meeting the needs and desires of patent applicants. Even in those systems which attempt to weed out unpatentable subject matter prior to registration,

²⁰⁹ *Parker, Acting Commissioner of Patents and Trademarks v Flook*, 437 US 584, 589-90 (1978) (“once the algorithm [was] assumed to be within the prior art, the application, considered as a whole, contained no patentable invention”).

²¹⁰ *Genentech* (invention of artificial trans-Plasminogen Activator was not excluded discovery “as such”, even though once discovery of amino acid sequences was known, the application was obvious).

²¹¹ In Europe, *Vicom/Computer-related invention*, T208/84 [1987] EPOR 74; [1987] OJEPO 14. In the United States, see *Diamond v. Diehr* 450 US 175, 188 (1981).

²¹² *Parker v Flook*, 437 US 584, 589-90 (1978) (limiting an abstract idea to one field of use or adding token post-solution components did not make the concept patentable); *Bilski v. Kappos*, 561 US ___ (2010, US S Ct) (limiting abstract idea of hedging to energy market did not make process patentable); *Classen Immunotherapies Inc v. Biogen Idec, GlaxoSmithKline and Merck & Co, Inc* (USCAFC, 2006) (adding step of immunizing patients did not make patentable).

²¹³ A number of commentators argue that scarce resources are best spent investigating novelty and non-obviousness rather than patentability: Michael Risch, ‘Everything is Patentable,’ 75 Ten L R 591, 658 (2008).

the truth remains that exclusions from patentability rarely offer the level of reassurance to users that might be desired.²¹⁴

In an example of dramatic under-statement, the US Court of Appeal for the Federal Circuit has described the task of differentiating patentable subject matter from unpatentable matter as an inquiry which is “hardly straightforward.”²¹⁵ An exclusion frequently ends up as one strand in complex and expensive counter-claim that a patent is invalid.

Moreover, the supposed certainty offered by exclusions is often illusory for a different reason: the invention may fall to be protected by some other intellectual property right or related action (such as unfair competition law). Aesthetic creations, excluded under many patent regimes, do not fall into the public domain, but are protected by copyright; ditto computer programs; and, where plants fall outside the patent system, international obligations in fact require the possibility of their protection under TRIPs.

G. REFLECTIONS AND THOUGHTS FOR THE FUTURE

This Introduction foresees a trend: the shift from “exclusions” to “exceptions.” To some extent the trend is already occurring. The historical survey shows a significant standardisation and limitation of exclusions, in particular as a result of TRIPs and regional patent granting arrangements; and an expansion in the use of exceptions (where there is less explicit international regulation). Moreover, courts and offices have encountered real difficulties applying exclusions, while commentators have been calling for greater attention to be paid to exceptions. Academics have suggested a number of potential defences; a “fair use” defence; an “interoperability” defence; a “necessity” defence.

Some commentators view the shift from exclusions to exceptions as a kind of legal evolution, reflective of increasing sophistication in understanding of how to balance the incentives provided by patents with the negative consequences they may have for the exploitation of inventions and the development of improvements. Indeed, Professor Duffy has argued (based on US experience) that

“the temporary rules of patentable subject matter might properly be viewed as experiments in adjusting and refining the patent system. The doctrinal area is a hotbed of evolution; it is where subtle intuitions about the patent system have an initial effect. Those intuitions are encoded into approximate rules, but in the long run, more nuanced and theoretically rigorous doctrine supplants the approximations.”²¹⁶

²¹⁴ But note John Allison and Emerson Tiller, ‘The Business Method Patents Myth,’ 18 Berk Tech LJ 987 (2003) (surveying business method patents granted by the USPTO and exposing “as a myth” the view that such patents are of lower quality)..

²¹⁵ *Prometheus Laboratories Inc v. Mayo Collaborative Services* (2008) (Lourie CJ).

²¹⁶ John F. Duffy, ‘Rules and standards on the Forefront of Patentability,’ (2009-10) 51 Wm & Mary L. Rev. 609, 652.

The idea that the shift is “evolutionary”, or the playing out of a “more theoretically rigorous” logic, however, should not be over-stated.²¹⁷ It is important to acknowledge asymmetries of power in the political economy of intellectual property, and the dangers of legislative and regulatory capture by economically powerful industries. Viewed from this perspective, it is equally plausible to characterise the shift from “exclusions” to “exceptions” in terms of loss to the public domain, reflecting the widely acknowledged problem that the “losers” are often widely dispersed interests, poorly represented before government.²¹⁸

While recognising the realities of lobbying, I have suggested in the concluding section of this introduction that, where there is a choice between utilising an “exclusion” and an “exception”, there are many things to be said for using exceptions. In particular, they can often offer more nuanced solutions, and ones which are more likely to be interpreted and applied affectively. This would likely be as true, perhaps more so, in relation to developing countries where the expenditure of resource ex ante on rigorous patent examination may seem to be a very low social priority. If ex ante examination is ineffective, establishing exceptions will give the public a more accurate idea of what it can and cannot do.

Moreover, in an era of overlapping intellectual property rights, there might be significant benefits with attempting to carve out freedoms that are applicable to a number of relevant rights. In Europe, the proposed Directive on Computer Implemented Inventions included an exception designed to facilitate interoperability. The latest proposal for the Community Patent would declare that there is no infringement of a community Patent where a person does an act that falls within the scope of articles 5 & 6 of the European Union Directive on the copyright protection of computer programs (the so-called “Software Directive”).²¹⁹ If a country recognised that exceptions to plant breeders’ rights (such as farmers privileges) also applied to patents, so that users’ traditional practices were not affected by the cumulation of patent and plant varieties’ regimes, there would likely be much less principled or practical objection to such cumulation. At a broader level, the shift to exceptions might valuably be welcomed as raising the possibility of greater recognition of “user’s rights”.

The potential for such a shift should not, however, be overstated. As the examination of rationales demonstrates, not all the reasons for excluding subject matter from protection can be adequately reflected in the provision of an exception. This is particularly the case with both the goal of delimiting the field of patentability and the tendency to refuse to grant immoral patents. These jobs cannot be done by adding exceptions to patentees’ rights. Moreover, in some cases there may be much to be said for the use of both exclusions and exceptions: the exceptions clarifying the

²¹⁷ Indeed the adoption of the medical practitioner exception has not put an end to arguments for a full exclusion of medical treatment from patentability:

²¹⁸ Note, for example, that the decision to introduce an exception for medical practitioners rather than an exclusion of medical methods from patentability reputedly reflected the influence of the biotechnology industry in the United States. And note John Thomas’s observation (‘The Patenting of the Liberal Professions,’ 40 BC L Rev 1139, at 1177 (1999) that “[f]ew occupations are as well-organized, imbued with a sense of profession and capable of employing the rhetoric of public service as the practice of medicine.”

²¹⁹ Council of the European Union, Revised Proposal for a Council Regulation on the Community Patent, 13706/09 (September 29., 2009), Art 9(i).

fundamental rights of users, for example, to utilise disembodied scientific theories or mathematical methods.

Moreover, experience in other fields, such as copyright, might also suggest that too much faith should not be placed in “exceptions”. One particularly difficult issue that has appeared on the copyright reform agenda in many countries in recent times is the extent to which statutory exceptions can be over-ridden by private contract. One can quite easily foresee similar issues arising in patent law, e.g. where supply of patented materials is coupled with detailed restrictions on use that interfere with statutory exceptions. If greater reliance does come to be placed on exceptions, particularly in effecting the careful balance between owners and the public, this issue will need to be confronted.

In addition, it should be acknowledged that our experience with exceptions is rather limited. One particular concern is precisely how much flexibility is left to national authorities as a result of Article 30 of TRIPs (in combination with the non-discrimination provisions of Article 27). Although that provision is somewhat open-textured, further guidance as to the level of flexibility it offers could be of real value. The WTO Panel in *Canadian Pharmaceuticals* gave helpful findings on the notion of “discrimination” between fields of technology, but other aspects of the holding (for example, that on the notion of “limited”) may operate to deprive member countries of the real potential offered by the use of exceptions. In our view, this would be regrettable.

Appendix A

Exclusions from Patentable Subject Matter

Discoveries	<p>Albania, Algeria,²²⁰ Andorra, Angola, Argentina, Australia, Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Chile, China,²²⁰ Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, Egypt, El Salvador, Estonia,²²¹ Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala,²²² Hungary, Iceland, India,²²³ Ireland, Italy, Jordan, Kenya, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico,²²⁴ Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Santa Lucia, Saudi Arabia, Serbia, Slovak Republic, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Former Yugoslav Republic of Macedonia, Tanzania, Trinidad & Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uruguay.</p> <p>[TOTAL: 78]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.</p>
Theories and/or principles	<p>Albania,²²⁵ Algeria, Andorra,²²⁵ Angola, Argentina,²²⁵ Armenia,²²⁵ Austria,²²⁵ Bahrain,²²⁵ Barbados,²²⁵ Belarus,²²⁵ Belgium,²²⁵ Belize,²²⁵ Bolivia,²²⁵ Bosnia & Herzegovina,²²⁵ Brazil,²²⁵ Bulgaria,²²⁶ Canada,²²⁷ Chile,²²⁵ Colombia,²²⁵ Costa Rica,²²⁵ Croatia,²²⁵ Cyprus,²²⁵ Dominica,²²⁵ Ecuador,²²⁵ Egypt,²²⁵ El Salvador,²²⁵ Estonia,²²⁵ Ethiopia, Finland,²²⁵ France,²²⁵ Georgia,²²⁵ Germany,²²⁵ Ghana,²²⁵ Greece,²²⁵ Guatemala,²²⁵ Hungary,²²⁵ Iceland,²²⁵ India,²²⁸</p>

²²⁰ Scientific discoveries.

²²¹ Including the description of the formation or development of the human body or a human gene sequence or part thereof.

²²² Simple discoveries.

²²³ Discoveries of a scientific principle or formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature; mere discovery of a new form of a known substance which does not enhance known efficiency, 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.

²²⁴ Discoveries that consist in making known or revealing something that already existed in nature, even though it was previously unknown to man.

²²⁵ Scientific theories.

²²⁶ Scientific theories and concepts.

²²⁷ Scientific principles and abstract theorems.

²²⁸ Discoveries of a scientific principle or formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.

	<p>Indonesia,²²⁹ Ireland,²²⁵ Italy,²²⁵ Jordan,²²⁵ Kenya,²²⁵ Kyrgyz Republic,²²⁵ Latvia,²²⁵ Lebanon, Lithuania,²²⁵ Luxembourg,²²⁵ Malaysia,²²⁵ Malta,²²⁵ Mauritius,²²⁵ Mexico,²³⁰ Moldova,²²⁵ Mongolia,²²⁵ Morocco,²²⁵ Mozambique,²²⁵ Netherlands,²²⁵ Nicaragua,²²⁵ Nigeria,²³¹ Norway,²²⁵ Oman,²²⁵ Pakistan,²²⁵ Panama,²³² Papua New Guinea,²²⁵ Peru,²²⁵ Philippines,²²⁵ Poland,²²⁵ Portugal,²²⁵ Qatar, Romania,²²⁵ Russian Federation,²²⁵ Santa Lucia,²²⁵ Saudi Arabia, Serbia,²²⁵ Slovak Republic,²²⁵ Slovenia,²²⁵ South Africa,²²⁵ Spain,²²⁵ Sri Lanka,²²⁵ Sweden,²²⁵ Syrian Arab Republic,²³³ Tanzania, Thailand,²³⁴ Former Yugoslav Republic of Macedonia,²²⁵ Trinidad & Tobago, Tunisia,²²⁵ Turkey,²²⁵ Uganda, United Kingdom,²²⁵ Uruguay,²²⁵ Uzbekistan.²²⁵ [TOTAL: 84]</p> <p>African Intellectual Property Organisation,²²⁵ Eurasian Patent Organisation,²²⁵ European Patent Organisation.²²⁵</p>
<p>Mathematical methods</p>	<p>Albania, Algeria, Andorra, Argentina, Armenia, Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria,²³⁵ Chile, Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana,²³⁶ Greece, Guatemala, Hungary, Iceland, India, Indonesia,²³⁷ Ireland, Italy, Jordan, Kenya, Kyrgyz Republic, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Norway, Oman, Pakistan, Papua New Guinea, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Saudi Arabia, Santa Lucia, Serbia, Slovak Republic, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Tanzania, Thailand,²³⁴ Former Yugoslav Republic of Macedonia, Trinidad & Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uruguay, Uzbekistan. [TOTAL: 80]</p> <p>African Intellectual Property Organisation, Eurasian</p>

²²⁹ Scientific and mathematical theories and methods.

²³⁰ Theoretical or scientific principles.

²³¹ Scientific principles.

²³² Theories and scientific principles.

²³³ The invention regards a purely theoretical or purely scientific method, without having a specific industrial application.

²³⁴ Scientific or mathematical rules or theories.

²³⁵ Mathematical methods and formulae.

²³⁶ Mathematical theories.

²³⁷ Scientific and mathematical theories and methods.

	Patent Organisation, European Patent Organisation.
Aesthetic creations	Albania, Algeria, Andorra, Argentina, Armenia, Australia, Austria, Belarus, Belgium, Bosnia & Herzegovina, Brazil, Bulgaria, ²³⁸ Canada, Costa Rica, Croatia, Cyprus, Finland, France, Georgia, ²³⁹ Germany, Greece, Guatemala, ²⁴⁰ Hungary, Iceland, India, Ireland, Kyrgyz Republic, Luxembourg, Malta, Mauritius, Mexico, Moldova, Morocco, Mozambique, Netherlands, Nicaragua, Norway, Pakistan, Panama, Philippines, Poland, Portugal, Romania, Russian Federation, Santa Lucia, Serbia, Slovak Republic, South Africa, Spain, Sri Lanka, Sweden, Former Yugoslav Republic of Macedonia, Trinidad & Tobago, Tunisia, Turkey, Ukraine, United Kingdom, Uruguay, Uzbekistan. [TOTAL: 59] African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.
Schemes, rules, methods etc for performing mental acts and/or intellectual activities	Albania, Algeria, Andorra, Argentina, Armenia, Austria, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, El Salvador, Estonia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India, Ireland, Italy, Kenya, Kyrgyz Republic, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Santa Lucia, Saudi Arabia, Serbia, Slovak Republic, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Former Yugoslav Republic of Macedonia, Tanzania, Trinidad & Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uzbekistan. [TOTAL: 75] African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.
Schemes, rules, methods etc for playing games	Albania, Algeria, Andorra, Argentina, Austria, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Chile, Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, El Salvador,

²³⁸ Results of artistic work.

²³⁹ Results of artistic design.

²⁴⁰ Pure aesthetic creations.

	<p>Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India, Ireland, Italy, Kenya, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal, Qatar, Romania, Russian Federation, Santa Lucia, Saudi Arabia, Serbia, South Africa, Spain, Sri Lanka, Sweden, Former Yugoslav Republic of Macedonia, Tanzania, Trinidad & Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uruguay. [TOTAL: 69]</p> <p>African Intellectual Property Organisation, European Patent Organisation.</p>
<p>Schemes, rules, methods etc for doing business and/or economic activity</p>	<p>Albania, Andorra, Argentina, Austria, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Bulgaria, Colombia, Costa Rica,²⁴¹ Croatia, Cyprus, Dominica, Ecuador, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala,²⁴² Hungary, Iceland, India, Ireland, Italy, Kenya, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua,²⁴³ Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Santa Lucia, Serbia, South Africa, Spain, Sri Lanka, Sweden, Syrian Arab Republic,²⁴⁴ Former Yugoslav Republic of Macedonia, Tanzania, Trinidad & Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uruguay. [TOTAL: 69]</p> <p>African Intellectual Property Organisation, European Patent Organisation.</p>
<p>Computer programs and/or software</p>	<p>Albania, Algeria, Andorra, Argentina, Austria, Belarus, Belgium, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Colombia, Costa Rica,²⁴⁵ Croatia, Cyprus, Ecuador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India,²⁴⁶ Ireland,</p>

²⁴¹ Schemes, rules or economic methods of advertisements or business.

²⁴² Schemes, principles, rules or economic methods of advertisements or business.

²⁴³ Economic, advertising and business plans.

²⁴⁴ The certificate of invention shall not be granted on financial schemes.

²⁴⁵ Computer programs as such.

²⁴⁶ Computer program per se.

	<p>Italy, Kyrgyz Republic, Latvia, Lithuania, Luxembourg, Malta, Mexico, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Norway, Panama, Peru, Philippines, Poland, Portugal,²⁴⁵ Qatar, Romania, Russian Federation, Santa Lucia, Serbia, Slovak Republic, Slovenia, South Africa, Spain, Sri Lanka, Sweden, Thailand, Former Yugoslav Republic of Macedonia, Tunisia, Turkey, United Kingdom, Uruguay, Uzbekistan. [TOTAL: 64]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.</p>
Algorithms	<p>Armenia,²⁴⁷ Belarus, Estonia, Georgia, India, Kyrgyz Republic, Moldova, Mongolia, Uzbekistan. [TOTAL: 9]</p> <p>Eurasian Patent Organisation.</p>
Presentation of information	<p>Albania, Algeria, Andorra, Argentina, Austria, Belarus, Belgium, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Colombia, Croatia, Cyprus, Ecuador, Estonia, Finland, France, Georgia, Germany, Ghana, Greece, Hungary, Iceland, India, Ireland, Italy, Kenya, Latvia, Lithuania, Luxembourg, Malta, Mexico, Morocco, Mozambique, Netherlands, Norway, Panama, Papua New Guinea, Peru, Poland, Portugal, Romania, Russian Federation, Santa Lucia, Serbia, Slovak Republic, South Africa, Spain, Sri Lanka, Sweden, Former Yugoslav Republic of Macedonia, Tanzania, Trinidad & Tobago, Tunisia, Turkey,²⁴⁸ Uganda, United Kingdom, Uruguay.²⁴⁹ [TOTAL: 57]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.</p>

²⁴⁷ Algorithms for computers.

²⁴⁸ Methods of collecting, arranging, presenting and transmitting information with no technical features.

²⁴⁹ Methods of reproducing information.

<p>Inventions contrary to law, public order, public policy, public interest and/or morality</p>	<p>Albania, Algeria, Andorra, Angola, Argentina, Austria, Bahrain, Barbados, Belarus,²⁵⁰ Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil,²⁵¹ Bulgaria,²⁵² Chile,²⁵³ Colombia, Costa Rica,²⁵⁴ Croatia, Cyprus, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France,²⁵⁵ Georgia,²⁵⁶ Germany, Ghana,²⁵⁷ Greece, Guatemala,²⁵⁸ Hungary, Iceland, India,²⁵⁹ Indonesia,²⁶⁰ Ireland, Italy, Japan,²⁶¹ Jordan, Kenya,²⁶² Kyrgyz Republic,²⁵⁰ Latvia, Lebanon, Liechtenstein, Lithuania,²⁵⁰ Luxembourg, Malaysia, Malta, Mauritius, Moldova, Mongolia,²⁶³ Morocco, Mozambique,²⁶⁴ Netherlands, Nicaragua, Nigeria, Norway,²⁶⁵ Oman, Pakistan, Panama,²⁶⁶ Papua New Guinea,²⁶⁷ Peru, Philippines, Poland, Portugal,²⁶⁸ Qatar, Republic of Korea,²⁶⁹ Romania,²⁷⁰ Russian Federation,²⁵⁰ Serbia,²⁷¹ Singapore,²⁷² Slovak</p>
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²⁵⁰ Inventions contrary to public interest, humanitarian principles or morality.

²⁵¹ Inventions contrary to morals, standards of respectability and public security, order and health.

²⁵² Inventions contrary to social order or morality.

²⁵³ Inventions contrary to the law, public policy, state security, morality or proper practice.

²⁵⁴ Inventions the commercial exploitation of which shall be forbidden for objective and necessary reasons to protect the *ordre public*, morality, health or life of persons or animals, or to preserve plants and to avoid severe damage to the environment.

²⁵⁵ Inventions contrary to the dignity of the human person, public policy or morality.

²⁵⁶ Inventions which may cause inhuman, immoral and/or anti-social action.

²⁵⁷ Inventions contrary to public order or morality; products and processes excluded by law for national security, economy, health or any other national concern.

²⁵⁸ Inventions the exploitation of which is contrary to *ordre public* and morality, provided that the contradiction to *ordre public* and morality shall not be considered merely by the reasons of prohibition, limitation and conditions by legal or administrative provisions.

²⁵⁹ Inventions use or commercial exploitation of which is contrary to law or morality.

²⁶⁰ Inventions contrary to rules, regulations, religious morality, public order or ethics.

²⁶¹ Inventions contrary to public order, morality or health.

²⁶² Inventions contrary to public order, morality, public health and safety, principles of humanity and environmental conservation.

²⁶³ Inventions contrary to public health or environmental protection.

²⁶⁴ Inventions contrary to morality, good behaviour, public safety, public order or public health.

²⁶⁵ Inventions whose exploitation would be contrary to morality or public order. Patents cannot on this basis be granted for *inter alia*: Processes for cloning humans; modifying the germ line genetic identity of humans; uses of human embryos for industrial or commercial purposes; and process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit, and animals resulting from such processes.

²⁶⁶ Inventions contrary to national laws, health, public policy, morality, proper practice or State security.

²⁶⁷ Inventions contrary to public order or morality or which seriously damage the environment.

²⁶⁸ Patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to the law, *ordre public*, public health or morality, an exploitation not being deemed to be prohibited merely because it is prohibited by law or administrative regulation.

²⁶⁹ Inventions contrary to public order or morality or damaging to public health.

²⁷⁰ Inventions, the exploitation of which would be contrary to public order or morality, including those being detrimental to human, animal or plant life, or health or the environment, the exclusion not being deemed to be prohibited merely because the exploitation is prohibited by law.

²⁷¹ Inventions contrary to public order or morality, in particular: processes for cloning humans; modifying the germ line genetic identity of humans; uses of human embryos for industrial or commercial purposes; and processes for modifying the genetic identity of animals which are likely to

	<p>Republic,²⁷³ Slovenia, South Africa,²⁷⁴ Spain, Sweden, Switzerland, Syrian Arab Republic,²⁷⁵ Tanzania, Thailand,²⁷⁶ Former Yugoslav Republic of Macedonia, Trinidad & Tobago, Tunisia, Turkey, United Kingdom, Uruguay, Uzbekistan.²⁷⁷ [TOTAL: 84]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.</p>
Plant and/or animal varieties	<p>Albania, Algeria, Armenia, Austria,²⁷⁸ Bahrain,²⁷⁸ Barbados, Belarus, Belgium,²⁷⁹ Bolivia, Bulgaria, Canada,²⁸⁰ Chile,²⁷⁸ China, Colombia, Costa Rica,²⁸¹ Croatia, Ecuador, Egypt, Estonia, Ethiopia, Finland,²⁸² France,²⁸³ Georgia, Germany, Ghana, Greece, Iceland, India,²⁸⁴ Indonesia,²⁸⁵ Ireland, Israel,²⁸⁶ Italy, Jordan,²⁷⁸ Kenya,²⁸⁷ Kyrgyz Republic, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta,²⁸⁸ Mauritius, Mexico,²⁸⁹ Mongolia,²⁹⁰ Mozambique,²⁹¹ Netherlands,²⁹² Nicaragua,²⁹³ Nigeria, Norway, Oman,²⁹⁴ Pakistan, Panama, Peru, Poland, Portugal, Qatar, Romania,²⁷⁸ Russian Federation, Serbia, Slovak</p>

cause them suffering without any substantial medical benefit, and animals resulting from such processes.

²⁷² Inventions encouraging offensive, immoral or anti-social behaviour.

²⁷³ Inventions contrary to public interest, including principles of humanity and morality.

²⁷⁴ Inventions which encourage offensive or immoral behaviour.

²⁷⁵ The certificate of invention shall not be granted on financial schemes, inventions openly violating the public order, ethics or constitutions and pharmaceutical combinations.

²⁷⁶ Inventions contrary to public order, morality, health or welfare.

²⁷⁷ Inventions contrary to public interests, principles of humanity and morality.

²⁷⁸ Other than microorganisms.

²⁷⁹ Plant species and plant and animal varieties.

²⁸⁰ Higher life forms.

²⁸¹ New varieties of plants will be protected by a special law.

²⁸² Other than inventions whose technical feasibility is not confined to a particular plant or animal variety.

²⁸³ Animal breeds and plant varieties.

²⁸⁴ Plants and animals in whole or any part thereof other than microorganisms, but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals.

²⁸⁵ Living creatures, other than microorganisms.

²⁸⁶ Plants and animal varieties, other than microbiological organisms not derived from nature.

²⁸⁷ Plant varieties, other than parts thereof and products of biotechnological processes.

²⁸⁸ Animal varieties.

²⁸⁹ Animal breeds and plant varieties.

²⁹⁰ Plant and animal varieties produced biologically, other than microbiological methods and products.

²⁹¹ Living beings and parts thereof, other than microbiological processes and products.

²⁹² Plant and animal varieties produced by biological processes for their production, other than permitted microbiological methods and products.

²⁹³ Animals.

²⁹⁴ Animals other than microorganisms.

	<p>Republic, South Africa, Spain, Sweden, Switzerland, Tanzania, Thailand,²⁹⁵ Former Yugoslav Republic of Macedonia, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, Uruguay, Uzbekistan. [TOTAL: 70]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.</p>
<p>Essentially biological processes for the production of plants and/or animals</p>	<p>Albania,²⁹⁶ Algeria, Austria,²⁹⁶ Bahrain, Barbados,²⁹⁶ Belgium,²⁹⁶ Bolivia,²⁹⁷ Bulgaria,²⁹⁶ Chile,²⁹⁶ Colombia,²⁹⁷ Costa Rica, Croatia,²⁹⁶ Ecuador,²⁹⁷ Egypt,²⁹⁸ Estonia,²⁹⁹ Ethiopia, Finland,³⁰⁰ France,³⁰¹ Georgia,²⁹⁶ Germany,²⁹⁶ Ghana,²⁹⁶ Greece,²⁹⁶ Guatemala,³⁰² Iceland,²⁹⁶ Indonesia,³⁰³ Ireland,²⁹⁶ Italy,²⁹⁶ Jordan,³⁰⁴ Latvia,²⁹⁶ Liechtenstein,²⁹⁶ Lithuania,²⁹⁶ Luxembourg,²⁹⁶ Malaysia,³⁰⁵ Malta,²⁹⁶ Mauritius, Mexico,³⁰⁶ Nicaragua,³⁰⁷ Nigeria,²⁹⁶ Norway,²⁹⁶ Oman,²⁹⁷ Pakistan,²⁹⁶ Panama,³⁰⁸ Peru,²⁹⁷ Poland,²⁹⁶ Portugal, Qatar, Romania, Saudi Arabia, Serbia,³⁰⁹ Slovak Republic,³¹⁰ South Africa,²⁹⁶ Spain,²⁹⁶ Sweden,²⁹⁶ Switzerland,²⁹⁶ Former Yugoslav Republic of Macedonia,²⁹⁶ Tanzania, Tunisia,³¹¹ Turkey,</p>

²⁹⁵ Animals, plants and extracts therefrom.

²⁹⁶ Other than microbiological processes and/or products.

²⁹⁷ Other than non-biological and microbiological processes.

²⁹⁸ Other than microorganisms and non-biological and microbiological processes.

²⁹⁹ Other than microbiological processes for deriving microorganisms.

³⁰⁰ Other than: (a) microbiological processes and products; (b) products consisting of or containing biological material; (c) processes producing, processing or using biological material; (d) biological material isolated from its natural environment or produced by a technical process even if previously occurring in nature.

³⁰¹ Essentially biological processes for producing plants and animals which require natural phenomena such as cross-breeding or selection.

³⁰² Biological process occurring in nature without human intervention, except microbiological process.

³⁰³ Biological processes for producing plant or animal, other than microbiological process.

³⁰⁴ Biological methods for reproducing plants and animals, other than microbiological methods.

³⁰⁵ Other than man-made living microorganisms and microbiological processes and products.

³⁰⁶ Essentially biological processes for the production, reproduction and propagation of plants and animals.

³⁰⁷ Biological processes for the production of plants and animals not involving human intervention, other than microbiological processes.

³⁰⁸ Essentially biological means of producing plants and animals contrary to morality or human integrity or dignity.

³⁰⁹ Other than: (a) biotechnological processes whose technical feasibility is not confined to a particular plant or animal variety; (b) microbiological and other technical process and products.

³¹⁰ Other than biotechnological processes and products and industrial microorganisms.

³¹¹ Other than biological methods used in medicine and their products.

	<p>Ukraine,²⁹⁶ Uganda, United Kingdom,³¹² Uruguay.²⁹⁶ [TOTAL: 57]</p> <p>African Intellectual Property Organisation,²⁹⁶ European Patent Organisation.²⁹⁶</p>
<p>Therapeutic, surgical and diagnostic methods for treating humans or animals</p>	<p>Albania, Algeria, Andorra, Argentina, Austria, Bahrain, Barbados, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Canada,³¹³ Chile, China,³¹⁴ Colombia, Costa Rica, Croatia, Dominica, Ecuador, Egypt, El Salvador, Estonia,³¹⁵ Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India,³¹⁶ Indonesia,³¹⁷ Ireland, Israel,³¹⁸ Italy, Japan,³¹⁹ Jordan, Kenya, Latvia,³²⁰ Lebanon, Liechtenstein,³²¹ Lithuania,³²² Luxembourg, Malaysia, Malta, Mauritius, Mexico, Mongolia,³²³ Morocco, Mozambique, Netherlands, Nicaragua, Norway, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal,³²⁴ Qatar, Romania, Santa Lucia, Saudi Arabia, Serbia, Singapore, Slovak Republic,³²⁵ Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland, Tanzania, Thailand,³²⁶ Former Yugoslav Republic of Macedonia, Trinidad & Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uruguay. [TOTAL: 79]</p> <p>African Intellectual Property Organisation, European Patent Organisation.</p>

³¹² Other than: (a) microbiological methods and products; (b) inventions whose technical feasibility is not confined to a particular plant or animal variety; (c) products consisting of or containing biological material; (d) processes producing, processing or using biological material; (e) biological material isolated from its natural environment or produced by a technical process, even if previously occurring in nature.

³¹³ Methods of medical treatment.

³¹⁴ Methods for diagnosis and treatment of diseases.

³¹⁵ Methods for treatment of the human or animal body and diagnostic methods practiced on the human or animal body.

³¹⁶ Any processes for medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatments of humans or any process for a similar treatment of animals or plants to render them free of disease or increase economic value.

³¹⁷ Methods of examination, treatment, medication, and/or surgery applied to humans and animals.

³¹⁸ Therapeutic treatment on the human body.

³¹⁹ Methods for the treatment of humans.

³²⁰ Therapeutic and surgical methods for treatment of humans or animals.

³²¹ In accordance with the agreements with Switzerland and the EEA.

³²² Methods of treatment of people and animals, diagnostics and prevention of diseases.

³²³ Methods of treatment, diagnosis and prophylaxis of human and animal diseases.

³²⁴ This provision shall not prevent the grant of patents for products, including substances and compounds, for use in any of such methods.

³²⁵ Methods for prevention, diagnosis and treatment of human and animal disease.

³²⁶ Methods of diagnosis, treatment or cure of human and animal diseases.

Organisational and management methods	Algeria, ³²⁷ Armenia, ³²⁸ Australia, ³²⁹ Brazil, ³³⁰ Chile, ³³¹ Egypt, ³³² Georgia, ³³³ Kyrgyz Republic, ³²⁸ Uruguay, ³³⁴ Uzbekistan. [TOTAL: 10] Eurasian Patent Organisation. ³²⁸
Symbols, schedules and rules	Armenia, Estonia, ³³⁵ Kyrgyz Republic, Moldova, ³³⁶ Uzbekistan. ³³⁷ [TOTAL: 5] Eurasian Patent Organisation.
Topographies of integrated circuits	Belarus, Estonia, ³³⁸ India, Kyrgyz Republic, Moldova, Russian Federation, Ukraine, Uzbekistan. [TOTAL: 8] Eurasian Patent Organisation.
Plans etc for buildings and land development	Armenia, ³³⁹ Estonia, ³⁴⁰ Georgia, ³⁴¹ Kyrgyz Republic, ³³⁹ Moldova, ³⁴² Uzbekistan. ³⁴³ [TOTAL: 6] Eurasian Patent Organisation. ³³⁹

³²⁷ Methods and systems of teaching, organisation, administration and management.

³²⁸ Methods of economic organisation and management.

³²⁹ Schemes, rules and plans.

³³⁰ Schemes, plans, principles or methods of a commercial, accounting, financial, educational, publishing, lottery or fiscal nature.

³³¹ Economic, financial, easily verified trade and taxation systems, methods, principles or plans.

³³² Programs and schemes.

³³³ Educational methods and systems, grammatical language systems; economic organisations and managing methods.

³³⁴ Business, accounting, financial, educational, publicity, lottery or taxation principles or methods.

³³⁵ Conventional signs.

³³⁶ Conventional signs, timetables and rules.

³³⁷ Designations, schedules and rules.

³³⁸ Integrated circuit layout designs.

³³⁹ Projects and plans for structures, buildings and land development.

³⁴⁰ Projects and schemes of structures, buildings and land development.

³⁴¹ Plans and schemes of structures, buildings, territories.

³⁴² Projects and plans for buildings and construction and for territorial planning.

³⁴³ Plans and diagrams for buildings, constructions and land.

<p>Inventions detrimental to human, animal or plant life or health and/or the environment</p>	<p>Algeria, Argentina, Bahrain, Barbados,³⁴⁴ Belize,³⁴⁴ Bolivia,³⁴⁵ Colombia,³⁴⁵ Costa Rica,³⁴⁶ Dominica,³⁴⁷ Ecuador,³⁴⁵ Egypt,³⁴⁷ Guatemala,³⁴⁸ India,³⁴⁹ Kyrgyz Republic,³⁵⁰ Mongolia,³⁵¹ Papua New Guinea,³⁵² Peru, Republic of Korea,³⁵³ Romania,³⁵⁴ Saudi Arabia, Trinidad & Tobago,³⁵⁵ Tunisia,³⁵⁶ Uruguay.³⁵⁷ [TOTAL: 22] Eurasian Patent Organisation.³⁵⁸</p>
<p>Ornamental works</p>	<p>Algeria, Tunisia, African Intellectual Property Organisation.</p>
<p>Works commonly protected by copyright</p>	<p>Argentina,³⁵⁹ Bolivia,³⁶⁰ Brazil,³⁶¹ Colombia,³⁶⁰ Costa Rica,³⁶² Ecuador,³⁶⁰ Ethiopia, Guatemala,³⁶³ India,³⁶⁴ Mauritius,³⁶⁵ Mexico,³⁶² Mozambique,³⁶² Nicaragua,³⁶² Pakistan,³⁶⁵ Panama,³⁶² Peru,³⁶⁰ Santa Lucia,³⁶⁵ South Africa,³⁶⁵ Spain,³⁶⁶ Trinidad & Tobago,³⁶⁵ Turkey,³⁶⁷ United Kingdom,³⁶⁵ Uruguay.³⁵⁹ [TOTAL: 22]</p>

³⁴⁴ Inventions the commercial exploitation of which would be detrimental to human or animal health, plant life or the environment.

³⁴⁵ Inventions the commercial exploitation of which would be detrimental to human, animal life or health, plant preservation or the environment.

³⁴⁶ Inventions the commercial exploitation of which shall be forbidden for objective and necessary reasons to protect the *ordre public*, morality, health or life of persons or animals, or to preserve plants and to avoid severe damage to the environment.

³⁴⁷ Inventions prejudicial to the environment or human, animal or plant life and health.

³⁴⁸ Inventions the commercial exploitation of which shall be prevented in order to preserve health or life of persons, animals, plants or the environment.

³⁴⁹ Inventions use or commercial of which causes serious prejudice to human, animal or plant life or health or to the environment.

³⁵⁰ Inventions detrimental to the environment.

³⁵¹ Inventions contrary to public health or environmental protection.

³⁵² Inventions contrary to public order or morality or which seriously damage the environment.

³⁵³ Inventions detrimental to public health.

³⁵⁴ Inventions, the exploitation of which would be contrary to public order or morality, including those being detrimental to human, animal or plant life, or health or the environment, the exclusion not being deemed to be prohibited merely because the exploitation is prohibited by law.

³⁵⁵ Inventions detrimental to human, animal or plant life or health or the environment.

³⁵⁶ Inventions whose exploitation is prejudicial to public health or the protection of the environment.

³⁵⁷ Inventions detrimental to public health, food supply, safety or the environment.

³⁵⁸ Inventions, the prevention 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.

³⁵⁹ Literary, artistic or scientific works.

³⁶⁰ Literary, artistic works and other works protected by copyright.

³⁶¹ Literary, architectural, artistic and scientific works.

³⁶² Literary and/or artistic works.

³⁶³ Pure aesthetic creations, literary and artistic works.

³⁶⁴ Literary, dramatic, musical or artistic work or any other aesthetic creation whatever.

³⁶⁵ Literary, dramatic, musical and/or artistic works.

³⁶⁶ Literary or artistic works or any other aesthetic creation and scientific works.

³⁶⁷ Literary and artistic works, scientific works.

	African Intellectual Property Organisation. ³⁶⁸
Materials occurring in nature	Argentina, ³⁶⁹ Bolivia, ³⁷⁰ Brazil, ³⁷¹ Chile, ³⁷² Colombia, ³⁷⁰ Ecuador, ³⁷⁰ Egypt, ³⁷³ Guatemala, ³⁷⁴ India, ³⁷⁵ Mexico, ³⁷⁶ Nicaragua, ³⁷⁷ Oman, ³⁷⁸ Panama, ³⁷⁹ Peru, ³⁷⁰ Portugal, ³⁸⁰ Thailand, ³⁸¹ Tunisia, ³⁸² Uruguay. ³⁸³ [TOTAL: 18]
Abstract ideas, natural phenomena, laws of nature	Australia, ³⁸⁴ Brazil, ³⁸⁵ United States. [TOTAL: 3]

³⁶⁸ Literary, architectural and artistic works.

³⁶⁹ Living material and substances already occurring in nature; biological and genetic material occurring in nature or derived therefrom by reproduction, and genetic reproduction processes replicating nature.

³⁷⁰ Natural biological materials.

³⁷¹ Natural living beings, in whole or in part, and biological material, including the genome or germplasm of any natural living being, when found in nature or isolated therefrom, and natural biological processes; living beings, in whole or in part, other than transgenic microorganisms.

³⁷² Part of living being as exists in nature, biological process, biological material existing in nature including genome and germplasm (nevertheless, where biological material or a product directly obtained therefrom meets the patentability requirements, is described adequately and the industrial applicability is described in the application, they are susceptible of patent protection).

³⁷³ Organs, tissues, live cells, natural biological substances, nucleic acids and genomes.

³⁷⁴ Materials and energies in the form which exist in nature.

³⁷⁵ Discoveries of a scientific principle or formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature.

³⁷⁶ Biological and genetic material as found in nature.

³⁷⁷ Substances and matter found in nature.

³⁷⁸ Natural substances; this provision shall not apply to the process of isolating those natural substances from their original environment.

³⁷⁹ Naturally occurring biological material.

³⁸⁰ Materials or substances which already exist in nature.

³⁸¹ Naturally occurring microorganisms and their components.

³⁸² Live substances occurring in nature.

³⁸³ Biological or genetic material occurring in nature.

³⁸⁴ Abstract ideas.

³⁸⁵ Abstract conceptions.

The human body and processes related to it	Australia, ³⁸⁶ Canada, ³⁸⁷ Estonia, ³⁸⁸ Finland, ³⁸⁹ France, ³⁹⁰ Mexico, ³⁹¹ Norway, ³⁹² Panama, ³⁹³ Portugal, ³⁹⁴ Romania, ³⁹⁵ Serbia, ³⁹⁶ Spain, ³⁸⁹ Sweden, ³⁸⁹ Switzerland, ³⁹⁷ United Kingdom. ³⁸⁹ [TOTAL: 15]
Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit, and animals resulting from such processes	Estonia, Finland, France, Norway, ³⁹⁸ Portugal, Serbia, Spain, Sweden, United Kingdom. [TOTAL: 9]
Inventions that are not new	New Zealand, ³⁹⁹ Syrian Arab Republic. [TOTAL: 2]

³⁸⁶ Humans and the biological processes for their generation.

³⁸⁷ Higher life forms.

³⁸⁸ Biological processes for cloning humans; modifying the genetic identity of humans; using human embryos for commercial purposes.

³⁸⁹ The human body, at any stage of its formation and development or the simple discovery of its elements, including gene sequences, other than elements isolated from the human body or produced by a technical process; processes for cloning humans; modifying the germ line genetic identity of humans; uses of human embryos for industrial or commercial purposes.

³⁹⁰ The human body, at any stage of its formation and development, as well as the mere discovery of one of its elements; processes for cloning human beings; for modifying the genetic identity of the human being; the use of human embryos for industrial or commercial purposes and complete or partial gene sequences.

³⁹¹ The human body and the living parts composing it.

³⁹² The human body, at any stage of its formation and development or the simple discovery of its elements, including gene sequences, other than elements isolated from the human body or produced by a technical process.

³⁹³ Live material forming part of the human body.

³⁹⁴ Processes for cloning human beings; processes for modifying the germ line genetic identity of human beings; uses of human embryos for industrial or commercial purposes; the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including a sequence or partial sequence of a gene, cannot constitute patentable inventions.

³⁹⁵ The human body, at any stage of its formation and development or the simple discovery of its elements, including the sequence or partial sequence of a gene.

³⁹⁶ The human body, at any stage of its formation and development or the simple discovery of its elements, including gene sequences; processes for cloning humans; modifying the germ line genetic identity of humans; uses of human embryos for industrial or commercial purposes. Also: inventions whose exploitation would be contrary to morality or public order. Patents cannot on this basis be granted for *inter alia*: Processes for cloning humans; modifying the germ line genetic identity of humans; uses of human embryos for industrial or commercial purposes; and process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit, and animals resulting from such processes.

³⁹⁷ Processes for forming chimeras and hybrids using human gametes or human totipotent cells; parthenogenic processes using germ line human material; processes for modifying the germ line genetic identity of human clones, hybrids, chimeras; parthenogenic offspring and germ line cells thus obtained; unmodified human stem cells and unmodified lines of stem cells.

³⁹⁸ Inventions whose exploitation would be contrary to morality or public order. Patents cannot on this basis be granted for *inter alia*: Processes for cloning humans; modifying the germ line genetic identity of humans; uses of human embryos for industrial or commercial purposes; and process for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit, and animals resulting from such processes.

The title of the invention submitted by the inventor intentionally demonstrates something which is not the invention itself	Syrian Arab Republic. [TOTAL: 1]
The invention's description, drawings, specifications and computations are not sufficient to put the invention into use	Syrian Arab Republic. [TOTAL: 1]
Nuclear substances and/or processes	Albania, ⁴⁰⁰ Brazil, ⁴⁰¹ China, ⁴⁰² India, ⁴⁰³ Mozambique, ⁴⁰⁴ Portugal. [TOTAL: 6]
Inventions contrary to the laws of nature	India, ⁴⁰⁵ Poland. ⁴⁰⁶ [TOTAL: 2]
New uses	Bolivia, ⁴⁰⁷ Chile, ⁴⁰⁸ Colombia, ⁴⁰⁷ Ecuador, ⁴⁰⁷ Oman, ⁴⁰⁹ Peru. ³⁹⁹ [TOTAL: 6]
Combinations or alterations of known products which do not function separately or produce a non-obvious result	Argentina, ⁴¹⁰ Chile, ⁴¹¹ Costa Rica, ⁴¹² India, ⁴¹³ Mexico, ⁴¹² Panama. ⁴¹⁴ [TOTAL: 6]

³⁹⁹ Inventions which are not a 'manner of new manufacture'.

⁴⁰⁰ Nuclear substances for military purposes.

⁴⁰¹ Nuclear processes and products.

⁴⁰² Nuclear products.

⁴⁰³ Inventions relating to atomic energy.

⁴⁰⁴ Atomic substances and processes.

⁴⁰⁵ Inventions which are frivolous or obviously contrary to well-established natural law.

⁴⁰⁶ Creations contrary to generally accepted scientific principles.

⁴⁰⁷ New uses of patented products and processes.

⁴⁰⁸ New uses of articles, objects or elements.

⁴⁰⁹ Known substances for which a new use has been discovered; this provision shall not apply to the use itself, where it constitutes an invention as defined in the law.

⁴¹⁰ Combinations which do not produce a non-obvious result.

⁴¹¹ Changes of shape, dimensions, proportions or materials which do not involve an essential alteration or solve a technical problem.

⁴¹² Juxtaposition of known inventions or mixtures of known products, or alteration of the form, use, dimensions or material thereof, except where in reality they are so combined or managed that they cannot function separately, or where their qualities or characteristic function have been so modified as to produce an industrial result not obvious to a person skilled in the art.

⁴¹³ Substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance; mere arrangement or re-arrangement or duplication of known devices each functioning independently in a known way.

⁴¹⁴ Combinations or alterations of known inventions and products which do not function separately or produce a non-obvious industrial result.

Inventions for the protection of human, animal or plant health or life or the preservation of the environment	Jordan, ⁴¹⁵ Kenya, ⁴¹⁶ Moldova, Nicaragua. [TOTAL: 4]
Plant products	Morocco. [TOTAL: 1]
Designs	Estonia, ⁴¹⁷ Latvia, Lithuania. ⁴¹⁸ [TOTAL: 3]
Invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties or traditionally known component(s)	India. [TOTAL: 1]
Agricultural and horticultural methods	India. [TOTAL: 1]
Biotechnological inventions which can be used solely for one particular plant or animal variety	Estonia. [TOTAL: 1]
Patents for pharmaceutical products and processes requiring the prior consent of the national agency	Brazil. [TOTAL: 1]
Sharia	Qatar, Saudi Arabia
Inventions incapable of practical realization or industrialization	Angola

⁴¹⁵ Inventions necessary to protect the life and health of humans, animals and plants or to avoid severe damage to the environment.

⁴¹⁶ Designated methods for the prevention or treatment of serious health hazards and life threatening diseases.

⁴¹⁷ Design solutions.

⁴¹⁸ Designs of products.

Appendix B Exceptions and Limitations of the Rights

<p>Acts concerning products produced and/or put into the market by or with the consent or the patent owner</p>	<p>Albania, Algeria,⁴¹⁹ Andorra, Argentina, Armenia, Barbados, Belarus,⁴²⁰ Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Chile,⁴²¹ China, Colombia, Costa Rica,⁴²² Croatia, Cyprus, Czech Republic, Denmark, Dominica, Ecuador, Egypt, El Salvador,⁴²³ Estonia, Ethiopia, Finland, France, Georgia, Ghana, Guatemala, Hungary, Iceland, India,⁴²⁴ Ireland,⁴²⁵ Kenya, Kyrgyz Republic, Latvia, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Nigeria,⁴²⁶ Norway, Oman, Pakistan, Panama,⁴²⁷ Papua New Guinea, Peru, Philippines, Poland, Romania, Russian Federation, Santa Lucia, Serbia, Singapore, South Africa,⁴²⁸ Spain, Sweden, Thailand, Trinidad & Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom,⁴²⁹ Uruguay, Uzbekistan.⁴³⁰ [TOTAL: 73]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation.</p>
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⁴¹⁹ Acts concerning products licitly put into commerce.

⁴²⁰ Acts concerning products lawfully put on the market.

⁴²¹ Commercial acts by third parties who adequately obtaining a product which was legitimately introduced in the market in any country by, or with consent of, the patent owner.

⁴²² Acts of sale, offering for sale, use, usufruct, import or any way of commercialisation of a patent-protected product or obtained by a patented process once it has been put on the market of any country with the patent holder's or the license holder's consent.

⁴²³ Marketing or use of products legally placed on the market in El Salvador.

⁴²⁴ Importation of patented products from a person who is duly authorised under the law to produce and sell or distribute the product.

⁴²⁵ Acts which cannot be prevented by the patent owner under EC law.

⁴²⁶ Acts in relation to products lawfully sold in Nigeria, other than acts specially provided for in the patent.

⁴²⁷ Acts concerning products lawfully put on the market.

⁴²⁸ Exhaustion.

⁴²⁹ Acts which cannot be prevented by the patent owner under the provisions of the Community Patent Convention relating to exhaustion of the rights.

⁴³⁰ Use of products lawfully introduced into civilian circulation.

<p>Acts for non-commercial/non-profit making purposes</p>	<p>Albania,⁴³¹ Algeria, Andorra,⁴³¹ Argentina,⁴³² Armenia,⁴³³ Bahrain,⁴³⁴ Belarus,⁴³¹ Belgium,⁴³¹ Bolivia,⁴³¹ Bosnia & Herzegovina,⁴³¹ Brazil,⁴³⁵ Bulgaria,⁴³⁵ Canada,⁴³¹ Colombia,⁴³¹ Costa Rica,⁴³⁶ Croatia,⁴³¹ Cyprus,⁴³⁵ Czech Republic, Denmark, Ecuador,⁴³¹ El Salvador,⁴³¹ Estonia,⁴³⁵ Ethiopia, Finland, France,⁴³¹ Georgia,⁴³¹ Germany,⁴³¹ Ghana,⁴³⁴ Greece,⁴³⁷ Guatemala,⁴³⁸ Hungary,⁴³¹ Iceland, Ireland,⁴³¹ Israel, Italy,⁴³¹ Japan, Kenya,⁴³⁹ Latvia, Lithuania,⁴³⁵ Luxembourg,⁴³¹ Malaysia,⁴³⁹ Malta,⁴³⁵ Moldova,⁴⁴⁰ Morocco,⁴³¹ Nicaragua,⁴³¹ Nigeria,⁴³⁹ Norway, Oman,⁴⁴¹ Panama,⁴³¹ Peru,⁴³¹ Philippines,⁴³⁵ Portugal,⁴³¹ Republic of Korea,⁴³⁹ Romania,⁴³¹ Russian Federation,⁴⁴² Santa Lucia,⁴³¹ Saudi Arabia, Serbia,⁴⁴³ Singapore,⁴³¹ Slovenia,⁴³¹ Spain,⁴³¹ Sri Lanka,⁴³⁹ Sweden, Switzerland,⁴³¹ Syrian Arab Republic,⁴⁴⁴ Former Yugoslav Republic of Macedonia,⁴³¹ Trinidad & Tobago,⁴³¹ Tunisia,⁴³¹ Turkey,⁴³⁹ Ukraine, United Kingdom,⁴³¹ Uruguay,⁴⁴⁵ Uzbekistan.⁴⁴⁶</p> <p>[TOTAL: 71]</p> <p>Eurasian Patent Organisation.⁴⁴⁷</p>
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⁴³¹ Private acts/uses for non-commercial/non-profit making purposes.

⁴³² Private or academic scientific or technological research for non-profit making experimental, testing or teaching purposes.

⁴³³ Personal use for non-profit making purposes.

⁴³⁴ Private use for non-industrial and non-commercial purposes.

⁴³⁵ Private acts/uses for non-commercial purposes not prejudicial to patent owner.

⁴³⁶ Legal acts of any nature done in a private environment and for non-commercial purposes.

⁴³⁷ Use for non-professional purposes.

⁴³⁸ Acts done in a private environment and for non-commercial purposes.

⁴³⁹ Acts/uses for non-industrial and non-commercial purposes.

⁴⁴⁰ Use for non-commercial purposes; use for private non-profit making purposes.

⁴⁴¹ Acts done privately and for non-commercial purposes in relation to patents granted for plants and plant varieties.

⁴⁴² Use for private, family, domestic or other non-business purposes not for profit.

⁴⁴³ Use for personal non-commercial purposes.

⁴⁴⁴ Acts that take place under special and non-commercial purposes and business-related purposes of scientific research.

⁴⁴⁵ Private acts for non-industrial and non-commercial purposes not prejudicial to the patent owner.

⁴⁴⁶ Non-profit use for personal reasons.

⁴⁴⁷ Private use for non-profit making purposes.

<p>Acts/uses for experimental, research and/or educational purposes</p>	<p>Albania, Algeria, Andorra, Argentina,⁴⁴⁸ Armenia, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia,⁴⁴⁹ Bosnia & Herzegovina, Brazil,⁴⁵⁰ Bulgaria,⁴⁵¹ Canada,⁴⁵¹ China, Colombia,⁴⁴⁹ Costa Rica,⁴⁵² Croatia,⁴⁵¹ Cyprus, Czech Republic,⁴⁵³ Denmark, Dominica, Ecuador,⁴⁴⁹ Egypt, El Salvador,⁴⁴⁹ Estonia, Ethiopia, Finland, France, Germany, Ghana, Greece, Guatemala,⁴⁵⁴ Hungary,⁴⁵⁵ Iceland, India,⁴⁵⁶ Indonesia,⁴⁵⁷ Ireland, Italy,⁴⁵⁸ Japan, Jordan,⁴⁵¹ Kenya, Kyrgyz Republic,⁴⁵⁹ Latvia,⁴⁶⁰ Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico,⁴⁶¹ Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua,⁴⁶² Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru,⁴⁴⁹ Philippines, Poland,⁴⁶³ Portugal,⁴⁶⁴ Republic of Korea, Romania, Russian Federation, Santa Lucia, Serbia,⁴⁶⁵ Singapore, Slovenia, Saudi Arabia, Spain, Sri Lanka, Sweden, Switzerland,⁴⁶⁶ Syrian Arab Republic,⁴⁶⁷ Thailand,⁴⁶⁸ Former Yugoslav Republic of Macedonia,⁴⁵¹ Trinidad & Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, Uruguay,⁴⁶⁹ Uzbekistan. [TOTAL: 86] African Intellectual Property Organisation, Eurasian Patent Organisation.</p>
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⁴⁴⁸ Private or academic scientific or technological research for non-profit making experimental, testing or teaching purposes.

⁴⁴⁹ Acts for experimentation, teaching or scientific or academic research.

⁴⁵⁰ Experimental acts for scientific or technological study or research.

⁴⁵¹ Acts/uses for research or development.

⁴⁵² Acts done for experimental purposes relating to the subject matter of the patented invention; acts done exclusively for the purpose of teaching or scientific or academic investigation with respect to the subject matter of the patented invention.

⁴⁵³ Acts relating to the subject matter of the invention done for experimental purposes including experiments and tests necessary, pursuant to the special legal regulation, before placing a medicine on the market.

⁴⁵⁴ Acts done exclusively for the purpose of experiments relating to the subject matter of the patented invention; acts done exclusively for the purpose of teaching or scientific or academic investigation, without commercial purposes, with respect to the subject matter of the patented invention.

⁴⁵⁵ Acts for experimental purposes, including experiments and tests necessary for the registration of medicines.

⁴⁵⁶ Use for purposes merely of experiment of research, including the imparting of instructions to pupils.

⁴⁵⁷ Use for purposes of education, research, experiment or analysis not prejudicial to the patent owner.

⁴⁵⁸ Private acts for experimental purposes.

⁴⁵⁹ Use for research or scientific experimentation purposes and manufacture, experimentation and testing of prototypes.

⁴⁶⁰ Use for scientific experiments or research purposes, and testing the invention.

⁴⁶¹ The right conferred by a patent shall not have any effect against any third party who, in the private and academic sphere and for non-commercial purposes, engages in scientific or technological research

Preparation of prescribed drugs, and related acts	Albania, ⁴⁷⁰ Andorra, ⁴⁷⁰ Armenia, ⁴⁷¹ Belarus, ⁴⁷¹ Belgium, ⁴⁷² Belgium, ⁴⁷² Bosnia & Herzegovina, ⁴⁷² Brazil, ⁴⁷³ Bulgaria, ⁴⁷¹ Croatia, ⁴⁷² Cyprus, ⁴⁷² Czech Republic, ⁴⁷² Denmark, ⁴⁷² Dominica, ⁴⁷² Estonia, ⁴⁷² Finland, ⁴⁷² France, ⁴⁷² Germany, ⁴⁷² Greece, ⁴⁷² Hungary, ⁴⁷² Iceland, ⁴⁷² India, ⁴⁷⁴ Ireland, ⁴⁷² Italy, ⁴⁷² Japan, ⁴⁷⁵ Latvia, ⁴⁷¹ Lithuania, ⁴⁷² Luxembourg, ⁴⁷² Malta, ⁴⁷² Moldova, Morocco, ⁴⁷² Netherlands, ⁴⁷² Norway, ⁴⁷² Philippines, ⁴⁷⁰ Poland, ⁴⁷⁶ Portugal, ⁴⁷⁷ Republic of Korea, ⁴⁷⁸ Russian Federation, ⁴⁷¹ Santa Lucia, ⁴⁷⁰ Serbia, ⁴⁷⁹ Singapore, ⁴⁸⁰ Slovak Republic, ⁴⁷⁶ Slovenia, ⁴⁷⁰ Spain, ⁴⁸¹ Sweden, ⁴⁷² Syrian Arab Republic, ⁴⁸² Thailand, ⁴⁷⁰ Former Yugoslav Republic of Macedonia, ⁴⁷² Trinidad &
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activities for purely experimental, testing or teaching purposes, and to that end manufactures or uses a product or process identical to the one patented.

⁴⁶² Acts for experimentation; acts for teaching or scientific or academic research purposes in relation to the subject matter of the patented invention.

⁴⁶³ Use for purposes of research, experiment, evaluation, analysis or teaching.

⁴⁶⁴ Acts done for experimental purposes relating to the subject matter of the patented invention including those for the preparation of the necessary administrative procedures for approval by the competent authorities, without, however, the ability to start industrial or commercial exploitation before verification of patent expiration.

⁴⁶⁵ Acts related to research and development, including acts obtaining an authorisation to market drugs and medicinal products.

⁴⁶⁶ Acts for experimental and research purposes to obtain knowledge about the subject of the invention including its possible uses; in particular all scientific research concerning the object of the invention is permitted; use of the invention for the purpose of teaching in educational establishments.

⁴⁶⁷ Acts that take place under special and non-commercial purposes and business-related purposes of scientific research.

⁴⁶⁸ Acts for purposes of study, research, experimentation or analysis.

⁴⁶⁹ Acts for experimental purposes (including acts anticipating future commercial exploitation) carried out within year before patent expiry; acts for teaching, scientific or academic research purposes.

⁴⁷⁰ Preparation of prescribed medicines in pharmacies or by medical professionals, and acts concerning those medicines.

⁴⁷¹ Preparation of prescribed medicines in pharmacies.

⁴⁷² Preparation of prescribed medicines in pharmacies, and acts concerning those medicines.

⁴⁷³ Preparation of prescribed medicines by a qualified person, and medicines so prepared.

⁴⁷⁴ Importation of medicines and drugs by the Government for its own use or for distribution in dispensaries, hospitals or other medical institutions maintained by, on behalf of or specified by the Government.

⁴⁷⁵ Preparation of patented medicines by mixing two or more medicines in accordance with the prescription of physicians and dentists, and medicines so prepared.

⁴⁷⁶ Preparation of prescribed medicines in pharmacies or by medical professionals.

⁴⁷⁷ Preparation in a pharmacy of a medicinal product according to a prescription in individual cases or acts concerning the medicinal product so prepared.

⁴⁷⁸ Manufacture of medicines in accordance with national law, and medicines so manufactured.

⁴⁷⁹ Preparation of prescribed drugs in pharmacies and placement of such drug on the market.

⁴⁸⁰ Preparation of prescribed medicines in pharmacies, and dealings with those medicines.

⁴⁸¹ The extemporaneous preparation of medicines in pharmacies carried out singly in making up a prescription and acts related to the medicines thus prepared.

⁴⁸² Preparation of medicine in pharmacy immediately and individually on the basis of medical prescription and work on formulas this way.

	<p>Tobago,⁴⁷² Tunisia,⁴⁷² Turkey,⁴⁷² United Kingdom,⁴⁷² Uruguay,⁴⁸³ Uzbekistan.⁴⁷¹ [TOTAL: 54]</p> <p>Eurasian Patent Organisation.⁴⁷¹</p>
<p>Continued prior use by person using the invention [in good faith] before the filing (priority) date, or was making preparations for such purposes.</p>	<p>Albania,⁴⁸⁴ Algeria, Andorra,⁴⁸⁴ Armenia, Australia, Austria, Bahrain,⁴⁸⁵ Barbados, Belarus, Belgium,⁴⁸⁶ Belize, Bolivia, Bosnia & Herzegovina,⁴⁸⁷ Brazil,⁴⁸⁸ Bulgaria, Canada,⁴⁸⁹ China, Colombia, Costa Rica,⁴⁹⁰ Croatia,⁴⁹¹ Czech Republic,⁴⁹² Denmark,⁴⁹³ Dominica,⁴⁸⁴ Ecuador, Egypt, El Salvador, Estonia,⁴⁹⁴ Ethiopia, Finland,⁴⁹³ France,⁴⁹⁵ Georgia,⁴⁹⁶ Germany,⁴⁹⁶ Greece,⁴⁹⁶ Hungary,⁴⁸⁴ Iceland,⁴⁹³ Indonesia,⁴⁹⁷ Ireland,⁴⁸⁴ Israel,⁴⁹⁸ Italy,⁴⁹⁹ Japan,⁵⁰⁰ Kenya,⁵⁰¹ Kyrgyz Republic, Latvia,⁵⁰¹ Liechtenstein, Lithuania, Luxembourg,⁵⁰² Malaysia, Malta,⁵⁰¹ Mauritius, Mexico, Moldova,⁴⁹⁸ Mongolia, Morocco, Mozambique, Netherlands,⁵⁰³ Nicaragua,⁵⁰¹ Nigeria,⁵⁰¹ Norway,⁴⁹³ Oman, Pakistan, Panama, Papua New Guinea,⁴⁹⁸ Peru, Philippines,⁵⁰¹ Poland,⁴⁹⁸ Qatar, Republic of Korea,⁵⁰⁴ Romania,⁵⁰⁵ Russian</p>

⁴⁸³ Preparation of prescribed medicines under the supervision of authorised professionals.

⁴⁸⁴ Prior use for commercial purposes.

⁴⁸⁵ Prior use for industrial exploitation.

⁴⁸⁶ Prior use or possession; no reference to making preparations.

⁴⁸⁷ Prior exploitation or manufacturing.

⁴⁸⁸ No reference to making preparations.

⁴⁸⁹ Continued prior use or sale by a person who, before the filing date (priority date), purchased, constructed or acquired the invention.

⁴⁹⁰ No reference to good faith or necessary preparations.

⁴⁹¹ Prior exploitation or manufacturing for business purposes.

⁴⁹² Continued prior use by a person who, before the filing date (priority date), had worked the invention independently of the inventor, or made preparation for that purpose.

⁴⁹³ Prior commercial exploitation.

⁴⁹⁴ Prior industrial use.

⁴⁹⁵ Continued prior use by a person who was, in good faith, in possession of the invention before the filing date (priority date).

⁴⁹⁶ No reference to good faith.

⁴⁹⁷ Prior exploitation, no reference to good faith or making preparations.

⁴⁹⁸ Prior exploitation.

⁴⁹⁹ Continued prior use by a person who used the invention in his business in the 12 months preceding the filing date (priority date).

⁵⁰⁰ Non-exclusive license available as of right in the case of prior use or working of the invention prior to the filing date (priority date).

⁵⁰¹ Prior use for business purposes.

⁵⁰² Continued prior use by a person who, in good faith before the filing date (priority date), possessed in Luxembourg a justified right in the prior use of the invention, and acts concerning the products thereof.

⁵⁰³ Prior use for business purposes independently of the patent owner; no reference to good faith.

⁵⁰⁴ Non-exclusive license for continued prior use by a person who, in good faith at the filing date (priority date), was commercially working the invention in the Republic of Korea, or had made preparations for that purpose.

	<p>Federation,⁵⁰⁶ Santa Lucia,⁴⁹⁸ Serbia,⁴⁹⁸ Singapore,⁴⁹⁸ Slovak Republic,⁵⁰⁷ Saudi Arabia, Spain,⁴⁸⁴ Sri Lanka,⁴⁹⁸ Sweden,⁴⁸⁴ Switzerland,⁵⁰⁸ Syrian Arab Republic,⁵⁰⁹ Thailand,⁵¹⁰ Former Yugoslav Republic of Macedonia,⁵¹¹ Tunisia, Turkey,⁵¹² Uganda, Ukraine,⁴⁸⁴ United Kingdom, United States,⁵¹³ Uruguay,⁴⁹⁸ Uzbekistan.⁵¹⁴ [TOTAL: 85]</p> <p>African Intellectual Property Organisation.⁴⁹⁸</p>
<p>Acts on or concerning foreign means of transport which temporarily or accidentally enter national territory</p>	<p>Albania, Algeria, Andorra, Argentina, Armenia, Australia, Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Bulgaria, Canada, China, Colombia, Croatia, Czech Republic, Denmark, Dominica, Ecuador, Egypt, Estonia, Ethiopia, Finland, Georgia, Germany, Ghana, Greece, Guatemala,⁵¹⁵ Iceland, Ireland, Japan, Kenya, Kyrgyz Republic, Latvia, Liechtenstein, Lithuania, Malaysia, Mauritius, Mexico,⁵¹⁶ Moldova, Mongolia, Morocco, Mozambique, Netherlands, New Zealand, Norway, Oman, Pakistan, Papua New Guinea, Peru, Philippines, Poland, Portugal,⁵¹⁷ Republic of Korea, Romania, Russian Federation, Santa Lucia, Serbia, Singapore, Slovak Republic,</p>

⁵⁰⁵ Prior use independent of the patent owner.

⁵⁰⁶ Prior conception and use independently of the patent owner.

⁵⁰⁷ Prior independent working; no reference to good faith.

⁵⁰⁸ Prior professional use.

⁵⁰⁹⁵⁰⁹ A person who has been manufacturing a product, using a method of making a particular product or arranging serious preparations for that purpose in Syria, in good faith, prior to the date of submission of a patent application from another person on the same product or method of manufacture may, despite the issuance of a patent right, continue to do so. The above benefit applies to continued use in its business, only in doing the same work without expansion, and the prior user may not waive the right to carry out these acts or may transfer this right only with other elements of the business.

⁵¹⁰ Reference to 'acquired equipment' instead of 'making preparations'.

⁵¹¹ Prior non-public use.

⁵¹² Prior working of the invention.

⁵¹³ As regards business method patents, continued use by a person who in good faith, had put the invention into practice at least one year before the filing date (priority date) and commercially used it before that date.

⁵¹⁴ Reference to prior independent use.

⁵¹⁵ Acts referred to in Article 5ter of the Paris Convention.

⁵¹⁶ The use of the patented invention in transportation vehicles of other countries when it forms part of such vehicles and when the vehicles are in transit on the national territory.

⁵¹⁷ Use on board of vessels of other Union or WTO members of the patented invention in the vessel's body, machinery, tackle and other accessories when it temporarily or accidentally enters this country provided that such invention is used exclusively for the needs of the vessel; use of the subject of the patent in the construction or operation of aircraft or land vehicles of other Union or WTO members, or of accessories of such aircraft or land vehicles, when those aircraft or land vehicles temporarily or accidentally enter national territory.

	<p>Slovenia, South Africa, Spain, Sri Lanka, Sweden, Switzerland,⁵¹⁸ Syrian Arab Republic,⁵¹⁹ Thailand, Former Yugoslav Republic of Macedonia, Trinidad & Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, United States, Uzbekistan. [TOTAL: 79]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation.</p>
<p>Compulsory licences</p>	<p>Albania, Algeria, Andorra, Argentina,⁵²⁰ Armenia, Australia,⁵²¹ Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece,⁵²² Guatemala, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Kenya, Kyrgyz Republic, Latvia, Lebanon, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, New Zealand, Nicaragua, Nigeria, Norway, Oman, Pakistan, Peru, Philippines, Poland, Qatar, Republic of Korea,⁵²³ Romania, Russian Federation, Saudi Arabia, Santa Lucia, Serbia, Singapore, Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Tanzania, Thailand, Former Yugoslav Republic of Macedonia, Trinidad & Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, Uruguay, Uzbekistan. [TOTAL: 90]</p> <p>African Intellectual Property Organisation, Eurasian Patent Organisation.</p>

⁵¹⁸ Vehicles temporarily in Switzerland and their equipment.

⁵¹⁹ Use of the invention in the means of road, sea or air transport of a State or entity members of the convention of industrial property in force in Syria or of a State under reciprocity, if any of these means temporarily or accidentally entered in Syria.

⁵²⁰ Exploitation by a third party allowed by the Office without authority of patent owner, subject to remuneration.

⁵²¹ Compulsory licences where necessary to meet reasonable requirements of the public or to remedy other anti-competitive practices, subject to remuneration.

⁵²² Non-contractual licences.

⁵²³ Non-exclusive licences in the public interest.

Exploitation and/or expropriation by or authorised by the government for national purposes	Albania, ⁵²⁴	Argentina, ⁵²⁵	Australia, ⁵²⁶	Austria, ⁵²⁷
	Barbados, ⁵²⁸	Belize, ⁵²⁹	Dominica, ⁵³⁰	Egypt, ⁵³¹
	Ethiopia,	Germany, ⁵³²	Ghana, ⁵³³	Hungary, ⁵³⁴
	India, ⁵³⁵	Indonesia, ⁵³⁶	Ireland, ⁵³⁷	Israel, ⁵³⁸
	Italy, ⁵³⁹	Kenya, ⁵⁴⁰	Lebanon,	Liechtenstein, ⁵⁴¹
	Lithuania, ⁵⁴²	Luxembourg, ⁵⁴³	Malaysia, ⁵⁴⁴	
	Malta, ⁵⁴⁵	Mauritius, ⁵⁴⁶	Morocco, ⁵⁴⁷	

⁵²⁴ Exploitation authorised by the Minister for the purposes of national security or public safety, subject to remuneration.

⁵²⁵ Exploitation ordered by the National Executive for purposes of health emergency or national security.

⁵²⁶ Exploitation or acquisition by the Commonwealth where necessary for the proper provision of services or in the interest of national security, subject to remuneration.

⁵²⁷ Expropriation by federal administrative authorities for the purposes of the armed forces, public welfare or other compelling federal interest, subject to payment of remuneration.

⁵²⁸ Exploitation authorised by the Minister in the interests of national security, national health, national nutrition, development of an essential sector of the national economy, or other public interest, subject to remuneration.

⁵²⁹ Exploitation authorised by the Minister in the public interest, in particular national security, nutrition, health, national nutrition and development of vital sectors of the national economy, subject to payment of remuneration.

⁵³⁰ Exploitation authorised by the Minister in the public interest, in particular for national security, nutrition, health or development of vital sectors of the national economy.

⁵³¹ Expropriation approved by ministerial committee for the purposes of national defense or in cases of emergency.

⁵³² Exploitation in the interest of public welfare or security ordered by the Federal Government or by, or on the instruction of, a supreme federal authority, subject to remuneration.

⁵³³ Exploitation by, or on behalf of a government agency, in the public interest, in particular, national security, health or development of vital sectors of the national economy.

⁵³⁴ Exploitation by the State or other party directed by the Minister, in event of an emergency due to national disaster, war or imminent risk of war, subject to remuneration.

⁵³⁵ Importation or manufacture of articles and uses of processes by, or on behalf of the Government for its own use.

⁵³⁶ Exploitation by the Government by Presidential Decree for the purposes of the defense and security of the State or urgent public interest.

⁵³⁷ Assignment by a Minister on behalf of the State, subject to remuneration.

⁵³⁸ Exploitation, authorised by the Minister, by a Government department or State contractor in the interests of national security or maintenance of essential supplies or services, subject to remuneration.

⁵³⁹ Exploitation, by Presidential decree, by the State, for national military defense or other public interest reasons, subject to remuneration.

⁵⁴⁰ Exploitation, ordered or authorized by the Minister, by a Government Ministry, Department, agency or other person, in the public interest (in particular, national security, nutrition, health, environmental conservation, or development of other vital sector of the national economy), not subject to remuneration.

⁵⁴¹ Exploitation by order of the Federal Council in the public interest.

⁵⁴² Exploitation, authorisation by Government resolution, by a central or local government institution, natural or legal person or enterprise without legal personality for the purposes of public need, national security, public health protection or development of an economically important sector, subject to remuneration.

⁵⁴³ Exploitation, licensed by Grand Ducal Order, in the public interest, subject to remuneration.

⁵⁴⁴ Exploitation by Federal or State Government, Ministry or Government department or any person authorised thereby, subject to remuneration.

⁵⁴⁵ Exploitation, authorised by the Minister, by a Government agency or designated person for national security or public safety, subject to remuneration.

⁵⁴⁶ Exploitation, authorised by the competent authority, by a Government agency or third person in the public interest (including, national security, nutrition, health or the development of other vital sectors of the national economy) subject to remuneration.

	<p>Netherlands,⁵⁴⁸ New Zealand,⁵⁴⁹ Nigeria,⁵⁵⁰ Norway,⁵⁵¹ Pakistan,⁵⁵² Papua New Guinea,⁵⁵² Philippines,⁵⁵² Poland,⁵⁵³ Republic of Korea,⁵⁵⁴ Santa Lucia,⁵⁵⁵ Singapore,⁵⁵⁶ South Africa,⁵⁵⁷ Sweden,⁵⁵⁸ Switzerland,⁵⁵⁹ Thailand,⁵⁶⁰ Trinidad & Tobago,⁵⁶¹ Tunisia,⁵⁶² Uganda, Ukraine,⁵⁶³ United Kingdom,⁵⁶⁴ Uruguay.⁵⁶⁵ [TOTAL: 44]</p> <p>African Intellectual Property Organisation.⁵⁶⁶</p>
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⁵⁴⁷ Exploitation, authorised by the competent authority, for the purposes of public health or the national economy; expropriation by order of the President of the Statutory Tribunal.

⁵⁴⁸ Exploitation, authorised by Royal Decree, for national defense.

⁵⁴⁹ Use for services of the Crown by, or authorised by, a Government Department, in particular for the purposes of national defense, security or emergency, subject to regulation.

⁵⁵⁰ Exploitation, authorised by the Minister, for the service of a government agency, in particular in a period of emergency.

⁵⁵¹ Assignment of the patent by the King to the Government or other designated party because of war or danger of war and crisis situations connected therewith, subject to remuneration.

⁵⁵² Exploitation, authorised by the Minister, by a Government agency or other person in the public interest (in particular national security, nutrition, health, or development of vital sectors of the national economy), subject to remuneration.

⁵⁵³ Exploitation for national purposes to prevent or eliminate a state of emergency relating to vital State interests (in particular security or public order), subject to remuneration.

⁵⁵⁴ Exploitation by, or authorised by, the Government for national defense or other emergency, subject to remuneration.

⁵⁵⁵ Exploitation by, or authorised, by a Government department, in particular for the purposes of public health, defense or atomic energy.

⁵⁵⁶ Exploitation authorised by a Government department, in particular in respect of national security, defence or civil defence emergency, subject to remuneration.

⁵⁵⁷ Compulsory assignment to the Minister of Defence of inventions relating to armaments.

⁵⁵⁸ Surrender of patent right, by Government decree, to the State or other designated party, in case of war or danger of war, subject to remuneration.

⁵⁵⁹ Expropriation of the patent by the Federal Council in the public interest.

⁵⁶⁰ Expropriation by the Prime Minister with the approval of the Cabinet, for the purposes of national defense or security, subject to remuneration.

⁵⁶¹ Exploitation, by a State agency or other person authorised by the Minister, for the services of the State in a national emergency or other circumstance of extreme urgency, subject to remuneration.

⁵⁶² Exploitation, by third parties authorised or ordered by the Minister, in the public interest (in particular, the national economy, safeguarding the environment or public health).

⁵⁶³ Use, by a person authorised by the Cabinet of Ministers, to protect the health of population, ecological safety or other public interests.

⁵⁶⁴ Exploitation, by a government department or other person authorised by the Secretary of State, in particular for the purposes of defence, medicines, atomic energy, war or other emergency.

⁵⁶⁵ Expropriation by the State in accordance with prescribed rules, in particular for the needs of the State; exploitation, by persons authorised by a special resolution of the Executive, in special situations (in particular, the general interest, defence or national security, the economic, social and technological development of strategic sectors, strategic, urgent health reasons or other public interest reasons), subject to remuneration.

⁵⁶⁶ Exploitation, by an administration or organisation authorised by the Minister of the Member State concerned, for the purposes of vital economic interest, public health, defence or the country's needs, subject to remuneration.

Exploitation authorised to counter anti-competitive practices	Argentina, ⁵⁶⁷ Australia, ⁵⁶⁸ Barbados, ⁵⁶⁹ Belize, ⁵⁶⁹ Chile, Dominica, ⁵⁷⁰ Pakistan, ⁵⁶⁹ Papua New Guinea, ⁵⁶⁹ Philippines, ⁵⁶⁹ Trinidad & Tobago. ⁵⁶⁹ [TOTAL: 9]
Other limited exceptions introduced at the reasoned request of a competent authority	Argentina. [TOTAL: 1]
Acts for obtaining regulatory approval	Australia, ⁵⁷¹ Bahrain, ⁵⁷² Canada, ⁵⁷³ Costa Rica, ⁵⁷⁴ Croatia, ⁵⁷⁵ Czech Republic, ⁵⁷⁶ Egypt, ⁵⁷⁷ France, ⁵⁷⁸ Germany, ⁵⁷⁹ Hungary, ⁵⁸⁰ India, ⁵⁸¹ Israel, ⁵⁸² Jordan, ⁵⁸³ Kenya, ⁵⁸⁴ Malaysia, ⁵⁸⁵ New Zealand, ⁵⁸⁶ Oman, ⁵⁸⁷ Poland, ⁵⁸⁸ Serbia, ⁵⁸⁹ South

⁵⁶⁷ Exploitation by a third party to counter anti-competitive practices.

⁵⁶⁸ Compulsory licences where necessary to meet reasonable requirements of the public or to remedy other anti-competitive practices, subject to remuneration.

⁵⁶⁹ Exploitation authorised by the Minister to counter anti-competitive exploitation, subject to remuneration.

⁵⁷⁰ Exploitation authorised by the Minister to counter anti-competitive exploitation.

⁵⁷¹ Acts for obtaining regulatory approval for pharmaceuticals.

⁵⁷² Acts for obtaining a license to market pharmaceutical products after patent expiration.

⁵⁷³ Acts of obtaining required regulatory approval for manufacture, construction, use or sale of a product under Canadian or foreign law.

⁵⁷⁴ The necessary use for investigation, processing or any other requirement for obtaining sanitary approval with a view to commercialise the product following patent expiration.

⁵⁷⁵ Acts for obtaining registration of the medical, veterinary and plant protection products.

⁵⁷⁶ Acts relating to the subject matter of the invention done for experimental purposes including experiments and tests necessary, pursuant to the special legal regulation, before placing a medicine on the market.

⁵⁷⁷ Acts for obtaining a license to market a product after patent expiration.

⁵⁷⁸ Studies and papers required to obtain authorisation for placing the medicinal product on the market, as well as the actions that are necessary to carry them out and to obtain authorisation.

⁵⁷⁹ Studies and trials necessary for obtaining pharmaceutical marketing authorisation.

⁵⁸⁰ Acts for experimental purposes, including experiments and tests necessary for the registration of medicines.

⁵⁸¹ Act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development or submission of information required under any law that regulates the manufacture, construction, use, sale or importation of any product.

⁵⁸² Experimental acts for obtaining a marketing license after patent expiration.

⁵⁸³ Use for obtaining marketing permits.

⁵⁸⁴ Acts necessary to obtain approval or registration for commercialising products after expiry of patent.

⁵⁸⁵ Acts related to development and submission of information to drug regulatory authority.

⁵⁸⁶ Development and submission of information for regulatory approval.

⁵⁸⁷ Acts of making, constructing, using or selling the patented invention solely for uses reasonably related to the development and submission of information required under any law of Oman or a country other than Oman that regulates the manufacture, construction, use or sale of any product.

⁵⁸⁸ Use for registration or marketing authorisation, in particular for pharmaceutical products.

⁵⁸⁹ Acts related to research and development, including acts obtaining an authorisation to market drugs and medicinal products.

⁵⁹⁰ Acts solely for the purpose reasonably related to the obtention, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

⁵⁹¹ Acts for obtaining a marketing authorisation for pharmaceutical products.

	Africa, ⁵⁹⁰ Switzerland, ⁵⁹¹ Syrian Arab Republic, ⁵⁹² Thailand, ⁵⁹³ Former Yugoslav Republic of Macedonia, Tunisia, ⁵⁹⁴ Turkey, ⁵⁹⁵ United States. ⁵⁹⁶ [TOTAL: 27]
Use in exceptional circumstances or <i>force majeure</i>	Belarus, Kyrgyz Republic, ⁵⁹⁷ Moldova, ⁵⁹⁸ Russian Federation, ⁵⁹⁹ Ukraine, ⁶⁰⁰ Uzbekistan. ⁶⁰¹ [TOTAL: 6]
Use of an essential element of the invention by a person unaware that it was for that purpose	Belgium, Dominica, Finland, Papua New Guinea. ⁶⁰² [TOTAL: 4]
Non-repeated use of biological material to obtain viable new material	Bolivia, ⁶⁰³ Colombia, ⁶⁰³ Ecuador, ⁶⁰³ Mexico, Nicaragua, Peru. ⁶⁰³ [TOTAL: 6]
Biological material put on the	Bolivia, ⁶⁰⁴ Brazil, ⁶⁰⁵ Colombia, ⁶⁰⁴ Denmark, ⁶⁰⁴

⁵⁹² To manufacture, install, use or sell a product during the term of protection in order to obtain a license to market the product in Syria after the expiry of patent protection.

⁵⁹³ Acts for registering pharmaceutical products for production, distribution or importation after patent expiration.

⁵⁹⁴ Acts relating to the manufacture of generic drugs for commercial exploitation after patent expiration.

⁵⁹⁵ Acts for obtaining a license to market medicines after patent expiration.

⁵⁹⁶ Solely for uses reasonably related to the development and submission of information under the Federal law which regulates the manufacture, use or sale of drugs and veterinary biological products, other than those products primarily manufactured using certain genetic manipulation techniques.

⁵⁹⁷ Use in exceptional circumstances (natural disasters, catastrophes, serious accidents), subject to payment of remuneration.

⁵⁹⁸ Use in extraordinary cases, such as natural disasters, catastrophes and epidemics or other circumstances of extreme urgency.

⁵⁹⁹ Use in emergency situations (natural calamities, catastrophes, accidents), subject to payment of remuneration.

⁶⁰⁰ Use in emergency conditions (natural disaster, accident, epidemic etc).

⁶⁰¹ Use in cases of natural calamities, disasters, epidemics and other exceptional circumstances.

⁶⁰² Acts performed by any person who proves that he was unaware that the patent existed.

⁶⁰³ Biological material other than plants.

⁶⁰⁴ Biological material obtained by reproduction, multiplication or propagation of the material put on the market by the patent owner for that purpose, other than for multiplication or propagation purposes.

⁶⁰⁵ Acts in respect of living material put on the market by the patent holder or licensee, other than for commercial multiplication or propagation of that living material.

⁶⁰⁶ Propagation or multiplication of biological material put on the market by, or with the consent of, the patent owner for that purpose, other than for other multiplication or propagation purposes, and biological material derived therefrom.

⁶⁰⁷ Propagation or multiplication of biological material put on the market in the EEA by, or with consent of, the patent owner for that purpose, other than for other multiplication or propagation purposes.

⁶⁰⁸ Biological material obtained by multiplication or propagation of the patented biological material put on the market of any country with the patent holder's or the license holder's consent with a condition that the multiplication or propagation necessarily results from the application for which the material was introduced to the commerce and that the material derived from such application is not used for the purpose of multiplication and propagation.

market by the patent holder, other than for propagation purposes	Ecuador, ⁶⁰⁴ Estonia, ⁶⁰⁶ Finland, ⁶⁰⁷ Guatemala, ⁶⁰⁸ Mexico, ⁶⁰⁹ Nicaragua, ⁶¹⁰ Norway, ⁶¹¹ Peru, ⁶⁰⁴ Serbia, ⁶¹² Sweden. ⁶¹³ [TOTAL: 14]
Non-commercial use of living material as an initial source of variation or propagation	Brazil. [TOTAL: 1]
Use by farmers of reproductive material for own agricultural activity	Denmark, ⁶¹⁴ Finland, ⁶¹⁴ France, ⁶¹⁴ Nicaragua, ⁶¹⁵ Norway, ⁶¹⁶ Oman, ⁶¹⁷ Sweden, ⁶¹⁶ Switzerland, ⁶¹⁸ United Kingdom. ⁶¹⁶ [TOTAL: 9]
A person who, after the lapse of a patent, has used the invention, or has made the necessary preparation for such use, may continue to use the invention in the same volume after the renewal of the patent	Bulgaria. [TOTAL: 1] Eurasian Patent Organisation. ⁶¹⁹

⁶⁰⁹ The right conferred by a patent shall not have any effect against a third party who, in the case of patents relating to products consisting of live material, uses, brings into circulation or markets the patented products for purposes other than multiplication or propagation, after the said products have been properly placed on the market by the owner of the patent or by a licensee.

⁶¹⁰ Biological material obtained by multiplication or propagation of the material put on the market by the patent owner for that purpose, but not used for multiplication or propagation purposes.

⁶¹¹ Biological material obtained by multiplication or propagation of the material put on the market in the EEA by the patent owner for that purpose, other than for multiplication or propagation purposes.

⁶¹² Biological material obtained by reproduction, multiplication or propagation of the material put on the market by the patent owner for that purpose, but not used for multiplication or propagation purposes without authorisation.

⁶¹³ Multiplication or propagation of biological material put on the market by the patent owner for that purpose, other than for further multiplication or propagation; biological material obtained by multiplication or propagation of the material put on the market in the EEA by the patent owner for that purpose, other than for multiplication or propagation purposes.

⁶¹⁴ Use by farmers of breeding stock or other animal reproductive material for own agricultural activity, but not sale for commercial reproduction; use by farmers of harvested plant propagating material for multiplication or propagation on own farm.

⁶¹⁵ Reproduction or propagation by farmers on their farms of products obtained from reproductive or vegetative propagating material, and marketing of these products for agricultural use or human consumption.

⁶¹⁶ Use by farmers of harvested plant propagating material for multiplication or propagation on own farm; use by farmers of breeding stock or other animal reproductive material for agricultural purposes on own farm, but not for sale for commercial reproduction.

⁶¹⁷ Within reasonable limits and safeguarding of the legitimate interests of the patent owner, any acts practised by farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the patented variety or an essentially derived variety.

⁶¹⁸ Farmers who acquired plant propagated material placed on the market by the patentee or with his consent may propagate on own farm the harvested product obtained from such material; farmers who acquired animals or animal productive material placed on the market by the patentee or with his consent may reproduce on own farm the animal raised from such acquired animals or material.

⁶¹⁹ Continued use by a person who in good faith has used or made necessary preparations for using an invention which is the subject of a published Eurasian patent application or Eurasian patent in the course of the period between the loss of rights to that application or patent and the publication of the

Use or sale of products obtained from a legitimate source but made and sold without authorisation of patent owner	China. [TOTAL: 1]
Indirect uses of production processes to obtain other products	Egypt, Syrian Arab Republic. [TOTAL: 2]
Acts not prejudicial to normal exploitation of the patent, or the interests of patent owner and third parties	Egypt, Syrian Arab Republic. [TOTAL: 2]
Objects and goods in transit through national territory	El Salvador, ⁶²⁰ Hungary, ⁶²¹ Poland. [TOTAL: 3]
Objects to be launched into space from French national territory	France. [TOTAL: 1]
Use of biological material for the purpose of breeding new varieties	Germany, ⁶²² Oman, ⁶²³ Switzerland. ⁶²⁴ [TOTAL: 3]
Products existing in the country before the filing date (priority date).	Japan, Netherlands, ⁶²⁵ Korea. [TOTAL: 3]
Acts committed before patent grant unless the application was already published, or the person concerned knew, or had been informed in writing, that the application had been filed	Thailand. [TOTAL: 1]
Variants or mutants of living forms or replicable living matter which are distinctively different from the patented original and deserve a separate patent	Kenya. [TOTAL: 1]
Acts in good faith by public authorities related to enforcement of intellectual property laws	Moldova. [TOTAL: 1]

mention of re-establishment of those rights. The right of subsequent use is applied only on the territory of a Contracting State where the subsequent use has taken place and the legislation of which provides for such a right.

⁶²⁰ Objects and goods in transit through national territory, but not put on the market there.

⁶²¹ Certain uses concerning means of communication and transport in transit in national territory, and foreign goods not intended to be put on the market there.

⁶²² Use of biological material for the purpose of breeding, discovery and development of new variety of plants.

⁶²³ Acts done for the purpose of breeding other varieties, including essentially derived varieties, in relation to patents granted for plants and plant varieties.

⁶²⁴ Use of biological material for the purposes of production, discovery or development of a plant variety.

⁶²⁵ Continued use of products manufactured before grant of the patent.

Use of biological material already existing in nature which is not necessary for the industrial application specified in the patent	Norway. [TOTAL: 1]
Exploitation by any person in the public interest, after three years from patent grant, where the supply to home market is of inadequate quality or quantity or excessively expensive.	Poland. [TOTAL: 1]
Acts provided for in art 27 of the Convention of International Civil Aviation	Portugal. [TOTAL: 1]
Exploitation in good faith or taking real and effective steps towards exploiting the invention by third parties in the interval between the patent owner's loss of rights and the reinstatement of the patent	Romania. [TOTAL: 1]
Exploitation by third parties of the invention or part of the invention in respect of which protection has been renounced	Romania. [TOTAL: 1]
Biological material obtained in the field of agriculture by chance or through an unavoidable technical process	Switzerland. [TOTAL: 1]
Importation or entry of small quantities of non-commercial goods in personal effects of passengers or sent in small packages	Uruguay. [TOTAL: 1]
General exception based on TRIPS article 30 wording	Egypt [TOTAL: 1]

[Annex II follows]