WIPO
Standing Committee on the Law of Patents

Exclusions from Patentability and Exceptions and Limitations to Patentees’ Rights

A Study Prepared by

Professor Lionel Bently,
Professor Brad Sherman,
Professor Denis Borges Barbosa
(with Ms Karin Grau-Kuntz),
Professor Shamnad Basheer
(with Mr Shashwat Purohit and Mr Prashant Reddy),
Professor Coenraad Visser and
Professor Richard Gold
(with Professor Yann Joly)
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”.

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* 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”).
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. 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 we build this 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, or examining specific copyright exceptions, such as those for libraries, for print disabled, and education. 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.” They concern, in effect, the definition of invention. In contrast, the Court of Appeal of England and Wales has expressed the view that ‘the categories are disparate with

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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 Fomete, 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 Dans 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.\textsuperscript{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.\textsuperscript{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

\textsuperscript{11} Aerotel [2007] RPC (7) 117 para 9; para 30.

\textsuperscript{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. 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.” 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.

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13 Jerome Reichman With Catherine Hasenzahl, Non-Voluntary Licensing of Patented Inventions (U.N. Conference on Trade & Dev. (UNCTAD) Issues Paper No. 5, 2002).
The lines of this study have thus been drawn rather arbitrarily, in as much as it is only concerned with two such policy levers. 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.

(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

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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.

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
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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. This phrase was interpreted by the courts, for example, from the late eighteenth century as excluding from protection “principles…” and for a long time there was doubt that it even included processes. 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”), and a number specifically required a demonstration of “utility”.

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.”
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….” This broad definition was, to some extent qualified by judicially developed doctrines— the so-called “moral utility doctrine”, and the exclusion from patentability of aspects of the “natural world”, discoveries, “unembodied inventions”, “handiwork of nature”, medical inventions, and “business methods.” Recently it has become common in the United States to limits 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.” Newfoundland, similarly, offered patents to those who discovered or made “any new and useful art, machine, manufacture or composition of matter not

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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 familiarly with State Street Bank & Trust Co v Signature Financial Group Inc, 149 F. 3d 1368 (Fed Cir 1998). See Gerard Maglioceca, ‘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.”

Lower and Upper Canada adopted the same definition in 1824 and 1826, and, in turn, in the Canadian Act Respecting Patents of Invention, 1869. 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.”

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 a 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.

<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Exclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1883</td>
<td>Britain</td>
<td>Patentable subject matter</td>
</tr>
<tr>
<td>1883</td>
<td>United States</td>
<td>Patentable subject matter</td>
</tr>
<tr>
<td>1883</td>
<td>British &amp; US colonies</td>
<td>Patentable subject matter</td>
</tr>
</tbody>
</table>

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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

<table>
<thead>
<tr>
<th>Food, beverages</th>
<th>Austria; Germany; Italy (art 37); Luxembourg; Sweden</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical; medicines</td>
<td>Argentine Republic; Austria; Finland; France; Germany; Italy; Luxembourg; Spain; Sweden33; Turkey; Venezuela</td>
</tr>
<tr>
<td>Substances produced by chemical processes</td>
<td>Germany; Luxembourg</td>
</tr>
<tr>
<td>Financial schemes</td>
<td>Argentine Republic; France; Mauritius; Spain; Turkey; Venezuela</td>
</tr>
<tr>
<td>Those of a mere theoretical nature; Inventions not relating to the manufacture of material objects; Scientific principles or purely scientific theorems</td>
<td>Argentine Republic; Brazil; France (art 30); Italy; Turkey; Venezuela; Italy; Austria; Canada (s.6) ; Finland; Russia (art 80); Spain</td>
</tr>
<tr>
<td>Use of natural products</td>
<td>Spain</td>
</tr>
<tr>
<td>Contrary to morals</td>
<td>Argentine Republic; Brazil; Colombia; Finland; France; Germany; Italy; Luxembourg; Mexico; Turkey; Venezuela</td>
</tr>
<tr>
<td>Contrary to laws</td>
<td>Argentine Republic; Austria; Brazil; British Guiana; Colombia; Finland; France; Germany; Italy; Luxembourg; Mexico; Portugal; Sweden; Turkey; Venezuela</td>
</tr>
<tr>
<td>Contrary to public health or safety</td>
<td>Austria; Brazil; Colombia (art 8) ; Finland; France; Italy; Mexico; Portugal (art 632); Russia (art 87); Turkey; Venezuela</td>
</tr>
<tr>
<td>“Prejudicial or Inconvenient...”</td>
<td>British Guiana; Ceylon (s.25); India (s. 16); Trinidad; GB; Mauritius (s. 17); New Zealand</td>
</tr>
<tr>
<td>Implements of war</td>
<td>Russia</td>
</tr>
<tr>
<td>Detriment to Government revenues</td>
<td>Russia (art 87)</td>
</tr>
</tbody>
</table>

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

33 Art 2 (permitting patents “for special methods of” making medicines or food.
35 para. 2.
offer an indication as to the relative prevalence of certain forms of exclusion at the time.

**Exclusions from Patentability c. 1987**

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

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.” Article 4 quarter contains only one notable limitation on subject matter:

“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...”\(^{39}\) Rule 39.1 of the Patent Cooperation 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;


\(^{37}\) Perhaps most obviously, the provision in the EC Biotechnology DirectiveArt. 6(2)(c); EPC Rule 23d(c), Implementing Regulations to the EPC (introduced by (1999) OJEP 437).

\(^{38}\) See Basheer et al.

\(^{39}\) *From GATT to TRIPS*, Straus 171.
(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 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

\begin{enumerate}
  \item 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.
  \item An invention may be, or may relate to, a product or process.
  \item The following, even if they are inventions within the meaning of subsection (1), shall be excluded from patent protection:
    \begin{enumerate}
      \item discoveries, scientific theories and mathematical methods;
      \item 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;
      \item schemes, rules or methods for doing business, performing purely mental acts or playing games;
      \item 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.
    \end{enumerate}
\end{enumerate}


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 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 |

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.”\textsuperscript{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.\textsuperscript{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).\textsuperscript{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…”\textsuperscript{46}

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

\textsuperscript{43} J. Straus, in F-K Beier & G. Schricker, \textit{From GATT to TRIPs} (VCH, 1996) 178.
\textsuperscript{44} C. Correa, \textit{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...”)
\textsuperscript{45} Correa, ibid.,271-2 (“Members have been left room to define ‘invention’ within their legal systems, in good faith...”)
\textsuperscript{46} P-T Stoll, J. Busche & K. Arend, \textit{WTO: Trade Related Aspects of Intellectual Property Rights} (2006), 479 (“Taking into account the diverse national approaches of Members concerning the interpretation of the concept of discovery, it cannot be ruled out that discoveries may be classified as inventions within the meaning of Article 27.”)
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

> “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;

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\(^{47}\) 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).
–(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…”
That said, some tribunals have shown a willingness to interpret Article 27 narrowly. In Classen Immunotherapies Inc v. Biogen Idec, GlaxoS
mKline 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).


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

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
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.\textsuperscript{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;
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.

\textsuperscript{51} Ibid.
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.
(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

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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.
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).
patents. Moreover, some set a maximum standard for the industrial applicability requirement (reflecting the US notion of “specific, substantial and credible” utility.”)  

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. 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 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

<table>
<thead>
<tr>
<th>Foreign Vessels</th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior use</td>
<td>Canada (s.7, foreign patents); Germany (Art 5); Luxembourg (art 5); Mauritius (s. 26); Sweden (art 16); US (?) (s.4899)</td>
</tr>
<tr>
<td>Government Use</td>
<td>Germany (Art 5); Luxembourg; South Australia (s.36)</td>
</tr>
<tr>
<td>Compulsory Licences for Non-working</td>
<td>GB(s.22)</td>
</tr>
<tr>
<td>Exhaustion</td>
<td>Italy (art 8, c.3)</td>
</tr>
</tbody>
</table>

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; |

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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).
* For short term patent.
<table>
<thead>
<tr>
<th>Three Years from grant</th>
<th>Spain; Turkey</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within first quarter of term (variable)</td>
<td>Russia</td>
</tr>
<tr>
<td>One year interruption</td>
<td>Brazil; Colombia; Finland</td>
</tr>
<tr>
<td>Two year interruption</td>
<td>Argentine Republic; Austria; Turkey Canada; France (Art 32); Italy; Portugal</td>
</tr>
<tr>
<td>Importation</td>
<td>Turkey</td>
</tr>
<tr>
<td>Refusal to License</td>
<td>Germany (Art 11.2); Luxembourg</td>
</tr>
<tr>
<td>Failure to supply Govt</td>
<td>New Zealand (s.23(3))</td>
</tr>
<tr>
<td>Public Good</td>
<td>Portugal (art 618)</td>
</tr>
</tbody>
</table>

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)**

<table>
<thead>
<tr>
<th>Experimental/Educational Use</th>
<th>86</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Use</td>
<td>85</td>
</tr>
<tr>
<td>Acts on or concerning foreign means of transport which temporarily or accidentally enter national territory</td>
<td>80</td>
</tr>
<tr>
<td>Exhaustion</td>
<td>73</td>
</tr>
<tr>
<td>Acts for non-commercial/non-profit making purposes</td>
<td>71</td>
</tr>
<tr>
<td>Preparation of prescribed drugs, and related acts</td>
<td>54</td>
</tr>
<tr>
<td>Exploitation and/or expropriation by or authorised by the government for national purposes</td>
<td>44</td>
</tr>
<tr>
<td>Bolar Exception</td>
<td>27</td>
</tr>
<tr>
<td>Biological material put on the market by the patent holder, other than for propagation purposes</td>
<td>14</td>
</tr>
<tr>
<td>Use by farmers of reproductive material for own agricultural activity</td>
<td>9</td>
</tr>
<tr>
<td>Exploitation authorised to counter anti-competitive practices</td>
<td>9</td>
</tr>
<tr>
<td>Non-repeated use of biological material to obtain viable new material</td>
<td>6</td>
</tr>
<tr>
<td>Use in exceptional circumstances or force majeure</td>
<td>6</td>
</tr>
<tr>
<td>Use of an essential element of the invention by a person unaware that it was for that purpose</td>
<td>4</td>
</tr>
<tr>
<td>Use of biological material for the purpose of breeding new varieties</td>
<td>3</td>
</tr>
<tr>
<td>Objects and goods in transit through national territory</td>
<td>3</td>
</tr>
<tr>
<td>Products existing in the country before the filing date (priority date)</td>
<td>3</td>
</tr>
<tr>
<td>Acts not prejudicial to normal exploitation of the patent, or the interests of patent owner and third parties</td>
<td>2</td>
</tr>
<tr>
<td>Indirect uses of production processes to obtain other products</td>
<td>2</td>
</tr>
<tr>
<td>Other limited exceptions introduced at the reasoned request of a competent authority</td>
<td>1</td>
</tr>
<tr>
<td>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</td>
<td>1</td>
</tr>
<tr>
<td>Description</td>
<td>Code</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>same volume after the renewal of the patent</td>
<td>1</td>
</tr>
<tr>
<td>Use or sale of products obtained from a legitimate source but made and sold without authorisation of patent owner</td>
<td>1</td>
</tr>
<tr>
<td>Objects to be launched into space from French national territory</td>
<td>1</td>
</tr>
<tr>
<td>Non-commercial use of living material as an initial source of variation or propagation</td>
<td>1</td>
</tr>
<tr>
<td>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</td>
<td>1</td>
</tr>
<tr>
<td>Variants or mutants of living forms or replicable living matter which are distinctively different from the patented original and deserve a separate patent</td>
<td>1</td>
</tr>
<tr>
<td>Acts in good faith by public authorities related to enforcement of intellectual property laws</td>
<td>1</td>
</tr>
<tr>
<td>Use of biological material already existing in nature which is not necessary for the industrial application specified in the patent</td>
<td>1</td>
</tr>
<tr>
<td>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.</td>
<td>1</td>
</tr>
<tr>
<td>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</td>
<td>1</td>
</tr>
<tr>
<td>Exploitation by third parties of the invention or part of the invention in respect of which protection has been renounced</td>
<td>1</td>
</tr>
<tr>
<td>Biological material obtained in the field of agriculture by chance or through an unavoidable technical process</td>
<td>1</td>
</tr>
<tr>
<td>Importation or entry of small quantities of non-commercial goods in personal effects of passengers or sent in small packages</td>
<td>1</td>
</tr>
</tbody>
</table>

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 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 ad 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

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60 *Pallin v Singer*, 36 USPQ 2d 1050 (D Vt, May 1, 1995)
exceptions (perhaps introducing a fair use concept) particularly to give full effect to fundamental rights of free speech.\footnote{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).}

**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 “Bolar exceptions” after the case that prompted the intervention of Congress.\footnote{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).} 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,\footnote{Christopher Heath, ‘The Patent Exemption for “Experimental Use” in Clinical Trials, Germany, Japan and the US Compared,’ (1997) 22 AIPPI J 267.} though in various forms. Some (like that in the United States) are confined to pharmaceuticals only,\footnote{See e.g. the European Union Directive 2004/27/EC of March 31, 2004 (regulatory approval).} while others are broader. The Canadian,\footnote{Acts of obtaining required regulatory approval for manufacture, construction, use or sale of a product under Canadian or foreign law.} Egyptian,\footnote{Egypt (Acts for obtaining a licence to market a product after patent expiration).} Indian,\footnote{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.} Israeli,\footnote{Israel (“Experimental acts for obtaining a marketing license after patent expiration”)} and Japanese exceptions,\footnote{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.”)} 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 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.

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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.
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 into force.74 For various

74 Holzapfel & J. Sarnoff, ‘A Cross-Atlantic Dialogue,’
reasons, this never in fact occurred. The latest, Revised proposal for a Council Regulation on the Community Patent includes and almost identical menu in Article 9, though it is supplemented by additional provisions on farmed saved seed, animal breeding and computer programs.\textsuperscript{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.

\textbf{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;…

(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.

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

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.
“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.” Moreover, in assessing whether an exception is “limited” the question is not the “economic impact” but impact on “rights”. Nor was the assessment a matter of “counting” how many rights (Make, sell, import) were affected. 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 7.35). In contrast the “regulatory review” exception was limited (para 7.45): “the extent of the acts unauthorised by the right holder that are permitted by it will be small and narrowly bounded.” 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.” 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

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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).
80 para 7.35.
81 para. 7.45.
82 para. 7.54.
“legal interests”. The WTO Panel rejected this. Instead, the Panel suggested that “legitimate” meant “‘justifiable’ in the sense that they are supported by relevant public policies or other social norms.” 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 emphasis on public health in the Doha Declaration), 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. 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”, “experiment or research”, “research or development”,

83 para. 7.68.
84 para 7.69.
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”.
89 Bulgaria; Croatia.
“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 finds that some, such as the United States, does not draw the 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 Professsor (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

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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”.
95 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.”)
96 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.”)
99 Ibid, 1351 (Fed Cir 2002).
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.\(^\text{100}\)

**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?

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.”\(^\text{101}\)

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.

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\(^{101}\) WT/DS114/R (Mar 17, 2000) para 7.94.
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 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

103 Andean Pact, Art 54; Antigua, s. 11(4)(1)(a).
104 The countries of the European Union, for example, apply regional exhaustion.
third party to counter anti-competitive practices, often conditioned on payment of remuneration.\textsuperscript{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.\textsuperscript{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.

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: \textsuperscript{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.

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


\textsuperscript{107} Decision 486, \textit{art} 53.
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. 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.

**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

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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.

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.

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109 T 315/03, Oncomouse, para 4.4:
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).
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 contract, 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:

(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:

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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”
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).
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.\(^\text{117}\)

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:\(^\text{118}\)

“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 \textit{Brenner v. Mason},\(^\text{119}\) 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 \textit{Bilski} has confirmed the three exclusions of “laws of nature”, “physical phenomena” and “abstract ideas”, though this shift has not been uncontroversial.\(^\text{120}\) 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.

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

\(^{117}\) 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 Metabon Laboratories, Inc (2006), at 126 (Breyer J).


\(^{120}\) \textit{Bilski v Kappos} 561 US __ (2010).
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.\(^\text{121}\) 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 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”\(^\text{122}\)

Similar arguments were being ventilated during the 1990s in Europe and more recently in relation to software and business methods.\(^\text{123}\) 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:

\(^{121}\) John F. Duffy, ‘Rules and standards on the Forefront of Patentability,’ (209-10) 51 Wm & Mary L. Rev. 609, 646.
\(^{122}\) Quoted in 409 US 63, 72 (1972.)
“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.”  

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

(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

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.”)
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.”).
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 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.

\(^{137}\) Community Trade Mark Regulation, Art 7(1)(e).
\(^{138}\) 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.’
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).

(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.159 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

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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.\textsuperscript{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.”\textsuperscript{141} In short, he suggests that the court should ask whether the “person having ordinary skill in the art” would consider the type of process at issue patentable.\textsuperscript{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.\textsuperscript{143}

\textsuperscript{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.”


\textsuperscript{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.”

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

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-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. 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…”

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146 548 US 124, 126-7.
(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.” 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 consequence of the European Union’s Biotechnology Directive, the Member States are obliged to exclude from patentability “processes for cloning human beings”, processes for modifying the germ line genetic identity of human beings, use of human embryos for industrial or commercial purposes, 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.’

While such exclusions from patentability are common, they are not universal. Other countries operate with no “morbidity” 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

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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.
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).
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 23(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)
Supreme Court referred to “a gruesome parade of horribles” 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. 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,” though another notes that the USPTO has, nevertheless, stated that it will not grant a patent over a human being. 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.”

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.” In fact, the opposite is true: patented inventions are subject to general law and regulation. 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.”

(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

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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.”
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.”)
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

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, 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. 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’. 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.

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. 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, predates the application of the exception on an absence of prejudice to the patentee.

The “calibration” or “balancing” dimension also is used to explain exceptions from research and scientific purposes. Here the argument is that even if the uses

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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.
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.”)
were public and commercial, uses for research and science are directed to producing new inventions or technology. 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.”

“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.

According to some, the notoriously narrow experimental use defence operating in the US has not caused significant difficulties (yet). 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, one scholar after another have stepped up to propose some sort of reform to provide the defence with greater flexibility. 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. 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. Professor Katherine Strandburg has proposed a combination of an exception for

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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…”).
“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).

(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.\textsuperscript{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.\textsuperscript{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 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.\textsuperscript{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;

\textsuperscript{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).

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

\textsuperscript{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.
(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)\textsuperscript{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.

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.

\textbf{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 it 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.

\textbf{(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 \textit{Festo Corp v Shoketsu Kinzoku Kogyo}

\textsuperscript{180} Strandberg has developed an interesting distinction between “user” and “seller” inventions: (2008) 79 U Colo LR
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 Bilski, 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.

181 Royal Society, Keeping Science Open (London, 2003) para. 3.5.
183 See e.g. CIPA President Alasdair Poore’s comments at http://www.cipa.org.uk/pages/press/article?D5C2CBED-894B-488B-ACD2-07B01E204A06
(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 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


\(^{188}\) Ibid, 618-9.
patentability.\textsuperscript{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.\textsuperscript{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.”\textsuperscript{191}

(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,\textsuperscript{192} as incentives to exploit,\textsuperscript{193} and as tools for the co-ordination of research activities (for example, linking basic research to clinical trial).\textsuperscript{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.

\textsuperscript{190} Ibid 462.
\textsuperscript{191} Ibid 468.
\textsuperscript{194} Paul Heald, ‘A Transaction Cost Theory of Patents’ on SSRN.
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 his invention know to those able to do so…”

(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

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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. 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.”

(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*. Whereas the minority was prepared to find a “business methods” exclusion from patentability, 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. 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 Stevens) considered this to be an inappropriate inference to draw from the addition of the exception to the statute book.

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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.
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.”)
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. 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.” 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.”

(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,” 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.”

Patentees, advised by skillful 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. 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. As a consequence, John Allison & Emerson Tiller argue against ex ante exclusions:

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200 149 F. 3d 1368.
201 Stevens at [34].
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.)
“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.” 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. 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 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. 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. Even where the case-law suggests that patentability should be judged by looking at the claimed invention “as a whole”, 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.

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

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…”).
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).
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 marketlet 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).
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. 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, the truth remains that exclusions from patentability rarely offer the level of reassurance to users that might be desired.

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.” 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.

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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).
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

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

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.”
computer programs (the so-called “Software Directive”). 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 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 couple 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.

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## Appendix A

### Exclusions from Patentable Subject Matter

<table>
<thead>
<tr>
<th>Discoveries</th>
<th>Albania, Algeria, Andorra, Angola, Argentina, Australia, Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia &amp; Herzegovina, Brazil, Bulgaria, Chile, China, Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India, Ireland, Italy, Jordan, Kenya, Latvia, Lebanon, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, 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 &amp; Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uruguay.</th>
</tr>
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<tr>
<th>Theories and/or principles</th>
<th>Albania, Algeria, Andorra, Angola, Argentina, Armenia, Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia &amp; Herzegovina, Brazil, Bulgaria, Chile, Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India.</th>
</tr>
</thead>
</table>

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.

| Mathematical theories and methods | 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, 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. 234 |

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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.
| Aesthetic creations                                                                 | Albania, Algeria, Andorra, Argentina, Armenia, Australia, Austria, Belarus, Belgium, Bosnia & Herzegovina, Brazil, Bulgaria, Canada, Costa Rica, Croatia, Cyprus, Finland, France, Georgia, Germany, Greece, Guatemala, 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. |
| Schemes, rules, methods etc for doing business and/or economic activity | Albania, Andorra, Argentina, Austria, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Bulgaria, Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India, Ireland, Italy, Kenya, Latvia, 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, South Africa, Spain, Sri Lanka, Sweden, Former Yugoslav Republic of Macedonia, Tanzania, Trinidad & Tobago, Tunisia, Turkey, Uganda, United Kingdom, Uruguay. [TOTAL: 69] African Intellectual Property Organisation, European Patent Organisation. |
| Computer programs and/or software | Albania, Algeria, Andorra, Argentina, Austria, Belarus, Belgium, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Colombia, Costa Rica, Croatia, Cyprus, Ecuador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India, Ireland, United Kingdom, Uruguay. [TOTAL: 69] African Intellectual Property Organisation, European Patent Organisation. |

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.
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<tr>
<td>Presentation of information</td>
<td>Albania, Algeria, Andorra, Argentina, Austria, Belarus, Belgium, Bolivia, Bosnia &amp; 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 &amp; Tobago, Tunisia, Turkey, 248 Uganda, United Kingdom, Uruguay. 249</td>
<td>African Intellectual Property Organisation, Eurasian Patent Organisation, European Patent Organisation.</td>
</tr>
</tbody>
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247 Algorithms for computers.
248 Methods of collecting, arranging, presenting and transmitting information with no technical features.
249 Methods of reproducing information.
| Inventions contrary to law, public order, public policy, public interest and/or morality | Albania, Algeria, Andorra, Angola, Argentina, Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Chile, Colombia, Costa Rica, Croatia, Cyprus, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India, Indonesia, Ireland, Italy, Japan, Jordan, Kenya, Kyrgyz Republic, Latvia, Lebanon, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal, Qatar, Republic of Korea, Romania, Russian Federation, Serbia, Singapore, Slovak |
| Plant and/or animal varieties | Albania, Algeria, Armenia, Austria, Barbados, Belarus, Belgium, Bolivia, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Ecuador, Egypt, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Iceland, India, Indonesia, Ireland, Israel, Italy, Jordan, Kenya, Kyrgyz Republic, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Mongolia, Mozambique, Netherlands, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Peru, Poland, Portugal, Qatar, Romania, Russian Federation, Serbia, Slovak |}

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.
<table>
<thead>
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<td>Albania, Algeria, Austria, Bahrain, Barbados, Belgium, Bolivia, Bulgaria, Chile, Colombia, Costa Rica, Croatia, Ecuador, Egypt, Estonia, Ethiopia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Iceland, Indonesia, Ireland, Italy, Jordan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Peru, Poland, Portugal, Qatar, Romania, Saudi Arabia, Serbia, Slovak Republic, South Africa, Spain, Sweden, Switzerland, Former Yugoslav Republic of Macedonia, Tanzania, Tunisia, Turkey.</td>
<td></td>
</tr>
</tbody>
</table>

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.
<table>
<thead>
<tr>
<th>Pharmacological, cosmetic, and industrial methods</th>
<th>Ukraine,296 Uganda, United Kingdom,312 Uruguay,296</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>[TOTAL: 57]</td>
</tr>
</tbody>
</table>

### Therapeutic, surgical and diagnostic methods for treating humans or animals

| Therapeutic, surgical and diagnostic methods for treating humans or animals | 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] |

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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.
<table>
<thead>
<tr>
<th>Category</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organisational and management methods</td>
<td>Algeria, Armenia, Australia, Brazil, Chile, Egypt, Georgia, Kyrgyz Republic, Uruguay.</td>
</tr>
<tr>
<td>Symbols, schedules and rules</td>
<td>Armenia, Estonia, Kyrgyz Republic, Moldova, Uzbekistan.</td>
</tr>
<tr>
<td>Topographies of integrated circuits</td>
<td>Belarus, Estonia, India, Kyrgyz Republic, Moldova, Russian Federation, Ukraine, Uzbekistan.</td>
</tr>
<tr>
<td>Plans etc for buildings and land development</td>
<td>Armenia, Estonia, Georgia, Kyrgyz Republic, Moldova, Uzbekistan.</td>
</tr>
</tbody>
</table>

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 Programmes 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.
| Inventions detrimental to human, animal or plant life or health and/or the environment | Algeria, Argentina, Bahrain, Barbados, Belize, Bolivia, Colombia, Costa Rica, Dominica, Ecuador, Egypt, Guatemala, India, Kyrgyz Republic, Mongolia, Papua New Guinea, Peru, Republic of Korea, Romania, Saudi Arabia, Trinidad & Tobago, Tunisia, Uruguay. [TOTAL: 22] | Eurasian Patent Organisation. 358 |
| Ornamental works | Algeria, Tunisia, African Intellectual Property Organisation. |
| Works commonly protected by copyright | Argentina, Bolivia, Brazil, Colombia, Costa Rica, Ecuador, Ethiopia, Guatemala, India, Mauritius, Mexico, Mozambique, Nicaragua, Pakistan, Panama, Peru, Santa Lucia, South Africa, Spain, Trinidad & Tobago, Turkey, United Kingdom, Uruguay. [TOTAL: 22] |

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.
<table>
<thead>
<tr>
<th>Materials occurring in nature</th>
<th>Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Egypt, Guatemala, India, Mexico, Nicaragua, Oman, Panama, Peru, Portugal, Thailand, Tunisia, Uruguay. [TOTAL: 18]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract ideas, natural phenomena, laws of nature</td>
<td>Australia, Brazil, United States. [TOTAL: 3]</td>
</tr>
</tbody>
</table>

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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. [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; parthenogenetic processes using germ line human material; processes for modifying the germ line genetic identity of human clones, hybrids, chimeras; parthenogenetic 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.
<table>
<thead>
<tr>
<th>Category</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>The title of the invention submitted by the inventor intentionally demonstrates something which is not the invention itself</td>
<td>Syrian Arab Republic. [TOTAL: 1]</td>
</tr>
<tr>
<td>The invention’s description, drawings, specifications and computations are not sufficient to put the invention into use</td>
<td>Syrian Arab Republic. [TOTAL: 1]</td>
</tr>
<tr>
<td>Nuclear substances and/or processes</td>
<td>Albania, Brazil, China, India, Mozambique, Portugal. [TOTAL: 6]</td>
</tr>
<tr>
<td>Inventions contrary to the laws of nature</td>
<td>India, Poland. [TOTAL: 2]</td>
</tr>
<tr>
<td>New uses</td>
<td>Bolivia, Chile, Colombia, Ecuador, Oman, Peru. [TOTAL: 6]</td>
</tr>
<tr>
<td>Combinations or alterations of known products which do not function separately or produce a non-obvious result</td>
<td>Argentina, Chile, Costa Rica, India, Mexico, Panama. [TOTAL: 6]</td>
</tr>
</tbody>
</table>

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

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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**

<table>
<thead>
<tr>
<th>Acts concerning products produced and/or put into the market by or with the consent or the patent owner</th>
<th>Albania, Algeria, 419 Andorra, Argentina, Armenia, Barbados, Belarus, 420 Belgium, Belize, Bolivia, Bosnia &amp; 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 &amp; Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, 429 Uruguay, Uzbekistan. 430</th>
</tr>
</thead>
</table>

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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.

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.
| Acts/uses for experimental, research and/or educational purposes | Albania, Algeria, Andorra, Argentina, Armenia, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia & Herzegovina, Brazil, Bulgaria, Canada, China, Colombia, Costa Rica, Croatia, Cyprus, Czech Republic, Denmark, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Germany, Ghana, Greece, Guatemala, Hungary, Iceland, India, Indonesia, Ireland, Italy, Japan, Jordan, Kenya, Kyrgyz Republic, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Portugal, Republic of Korea, Romania, Russian Federation, Santa Lucia, Serbia, Singapore, Slovenia, Saudi Arabia, Spain, Sri Lanka, Sweden, Switzerland, Syrian Arab Republic, Thailand, Former Yugoslav Republic of Macedonia, Trinidad & Tobago, Tunisia, Turkey, Uganda, Ukraine, United Kingdom, Uruguay, Uzbekistan. [TOTAL: 86] African Intellectual Property Organisation, Eurasian Patent Organisation. |

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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, Armenia, Belarus, Belgium, Bosnia & Herzegovina, Brazil, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Dominica, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, India, Ireland, Italy, Japan, Latvia, Lithuania, Luxembourg, Malta, Moldova, Morocco, Netherlands, Norway, Philippines, Poland, Portugal, Republic of Korea, Russian Federation, Santa Lucia, Serbia, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Syrian Arab Republic, Thailand, Former Yugoslav Republic of Macedonia, Trinidad & Tobago.

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.
<table>
<thead>
<tr>
<th>Continued prior use by person using the invention [in good faith] before the filing (priority) date, or was making preparations for such purposes.</th>
<th>Tobago, Tunisia, Turkey, United Kingdom, Uruguay, Uzbekistan. [TOTAL: 54] Eurasian Patent Organisation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albania, Algeria, Andorra, Armenia, Australia, Austria, Bahrain, Barbados, Belarus, Belgium, Belize, Bolivia, Bosnia &amp; Herzegovina, Brazil, Bulgaria, Canada, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, Dominica, Ecuador, Egypt, El Salvador, Estonia, Ethiopia, Finland, France, Georgia, Germany, Greece, Hungary, Iceland, Indonesia, Ireland, Israel, Italy, Japan, Kenya, Kyrgyz Republic, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Mauritius, Mexico, Moldova, Mongolia, Morocco, Mozambique, Netherlands, Nicaragua, Nigeria, Norway, Oman, Pakistan, Panama, Papua New Guinea, Peru, Philippines, Poland, Qatar, Republic of Korea, Romania, Russian</td>
<td></td>
</tr>
</tbody>
</table>

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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.
| Acts on or concerning foreign means of transport which temporarily or accidentally enter national territory | 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] African Intellectual Property Organisation. 498 |

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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.
509 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.

| Compulsory licences | Albania, Algeria, Andorra, Argentina, Armenia, Australia, 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, 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, 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] African Intellectual Property Organisation, Eurasian Patent Organisation. |

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

<table>
<thead>
<tr>
<th>Albania</th>
<th>Argentina</th>
<th>Australia</th>
<th>Austria</th>
<th>Barbados</th>
<th>Belize</th>
<th>Dominica</th>
<th>Egypt</th>
<th>Ethiopia</th>
<th>Germany</th>
<th>Ghana</th>
<th>Hungary</th>
<th>India</th>
<th>Indonesia</th>
<th>Ireland</th>
<th>Israel</th>
<th>Italy</th>
<th>Kenya</th>
<th>Lebanon</th>
<th>Liechtenstein</th>
<th>Lithuania</th>
<th>Luxembourg</th>
<th>Malaysia</th>
<th>Malta</th>
<th>Mauritius</th>
<th>Morocco</th>
</tr>
</thead>
</table>

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.
| Country                          | 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. | Exploitation, authorised by Royal Decree, for national defense. | 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. | Exploitation, authorised by the Minister, for the service of a government agency, in particular in a period of emergency. | 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. | 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. | 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. | Exploitation by, or authorised by, the Government for national defense or other emergency, subject to remuneration. | Exploitation by, or authorised, by a Government department, in particular for the purposes of public health, defense or atomic energy. | Exploitation authorised by a Government department, in particular in respect of national security, defence or civil defence emergency, subject to remuneration. | Compulsory assignment to the Minister of Defence of inventions relating to armaments. | 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. | Expropriation of the patent by the Federal Council in the public interest. | Expropriation by the Prime Minister with the approval of the Cabinet, for the purposes of national defense or security, subject to remuneration. | 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. | 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). | Use, by a person authorised by the Cabinet of Ministers, to protect the health of population, ecological safety or other public interests. | 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. | 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. | 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. |

<table>
<thead>
<tr>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Netherlands, New Zealand, Nigeria, Norway, Pakistan, Papua New Guinea, Philippines, Poland, Republic of Korea, South Africa, Sweden, Switzerland, Thailand, Trinidad &amp; Tobago, Tunisia, Uganda, Ukraine, United Kingdom, Uruguay</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exploitation authorised to counter anti-competitive practices</th>
<th>Argentina, Barbados, Belize, Chile, Dominica, Pakistan, Papua New Guinea, Philippines, Trinidad &amp; Tobago [TOTAL: 9]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other limited exceptions introduced at the reasoned request of a competent authority</td>
<td>Argentina. [TOTAL: 1]</td>
</tr>
<tr>
<td>Acts for obtaining regulatory approval</td>
<td>Australia, Bahrain, Canada, Costa Rica, Croatia, Czech Republic, Egypt, France, Germany, Hungary, India, Israel, Jordan, Kenya, Malaysia, New Zealand, Oman, Poland, Serbia, South</td>
</tr>
</tbody>
</table>

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.
<table>
<thead>
<tr>
<th>Use in exceptional circumstances or force majeure</th>
<th>Belarus, Kyrgyz Republic, 597 Moldova, 598 Russian Federation, 599 Ukraine, 600 Uzbekistan. [TOTAL: 6]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of an essential element of the invention by a person unaware that it was for that purpose</td>
<td>Belgium, Dominica, Finland, Papua New Guinea. 602 [TOTAL: 4]</td>
</tr>
<tr>
<td>Non-repeated use of biological material to obtain viable new material</td>
<td>Bolivia, 603 Colombia, 604 Ecuador, 605 Mexico, Nicaragua, Peru. 603 [TOTAL: 6]</td>
</tr>
<tr>
<td>Biological material put on the market by the patent holder for that purpose</td>
<td>Bolivia, 603 Brazil, 604 Colombia, 604 Denmark. 634</td>
</tr>
</tbody>
</table>

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 holder 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.
<table>
<thead>
<tr>
<th>Description</th>
<th>Countries</th>
</tr>
</thead>
</table>
| market by the patent holder, other than for propagation purposes           | Ecuador,  
Finland,  
Guatemala,  
Mexico,  
Nicaragua,  
Norway,  
Peru,  
Serbia,  
Sweden.  [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,  
Finland,  
France,  
Nicaragua,  
Norway,  
Oman,  
Switzerland,  
United Kingdom.  [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] |

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
<table>
<thead>
<tr>
<th>Description</th>
<th>Country/Region</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use or sale of products obtained from a legitimate source but made and sold without authorisation of patent owner</td>
<td>China. [TOTAL: 1]</td>
</tr>
<tr>
<td>Indirect uses of production processes to obtain other products</td>
<td>Egypt, Syrian Arab Republic. [TOTAL: 2]</td>
</tr>
<tr>
<td>Acts not prejudicial to normal exploitation of the patent, or the interests of patent owner and third parties</td>
<td>Egypt, Syrian Arab Republic. [TOTAL: 2]</td>
</tr>
<tr>
<td>Objects and goods in transit through national territory</td>
<td>El Salvador,(^6)(^2) Hungary,(^6)(^2) Poland. [TOTAL: 3]</td>
</tr>
<tr>
<td>Objects to be launched into space from French national territory</td>
<td>France. [TOTAL: 1]</td>
</tr>
<tr>
<td>Use of biological material for the purpose of breeding new varieties</td>
<td>Germany,(^6)(^2)(^2) Oman,(^6)(^2) Switzerland. [TOTAL: 3]</td>
</tr>
<tr>
<td>Products existing in the country before the filing date (priority date).</td>
<td>Japan, Netherlands,(^6)(^2) Korea. [TOTAL: 3]</td>
</tr>
<tr>
<td>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</td>
<td>Thailand. [TOTAL: 1]</td>
</tr>
<tr>
<td>Variants or mutants of living forms or replicable living matter which are distinctively different from the patented original and deserve a separate patent</td>
<td>Kenya. [TOTAL: 1]</td>
</tr>
<tr>
<td>Acts in good faith by public authorities related to enforcement of intellectual property laws</td>
<td>Moldova. [TOTAL: 1]</td>
</tr>
</tbody>
</table>

\(^6\)\(^2\)\(^2\)\(^2\) Objects and goods in transit through national territory, but not put on the market there.
\(^6\)\(^2\)\(^2\)\(^2\)\(^2\) 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.
\(^6\)\(^2\)\(^2\)\(^2\) Use of biological material for the purpose of breeding, discovery and development of new variety of plants.
\(^6\)\(^2\)\(^2\)\(^2\) Acts done for the purpose of breeding other varieties, including essentially derived varieties, in relation to patents granted for plants and plant varieties.
\(^6\)\(^2\)\(^2\)\(^2\)\(^2\) Use of biological material for the purposes of production, discovery or development of a plant variety.
\(^6\)\(^2\)\(^2\)\(^2\)\(^2\)\(^2\) Continued use of products manufactured before grant of the patent.
<table>
<thead>
<tr>
<th>Description</th>
<th>Country</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of biological material already existing in nature which is not necessary for the industrial application specified in the patent</td>
<td>Norway.</td>
<td>1</td>
</tr>
<tr>
<td>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.</td>
<td>Poland.</td>
<td>1</td>
</tr>
<tr>
<td>Acts provided for in art 27 of the Convention of International Civil Aviation</td>
<td>Portugal.</td>
<td>1</td>
</tr>
<tr>
<td>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</td>
<td>Romania.</td>
<td>1</td>
</tr>
<tr>
<td>Exploitation by third parties of the invention or part of the invention in respect of which protection has been renounced</td>
<td>Romania.</td>
<td>1</td>
</tr>
<tr>
<td>Biological material obtained in the field of agriculture by chance or through an unavoidable technical process</td>
<td>Switzerland.</td>
<td>1</td>
</tr>
<tr>
<td>Importation or entry of small quantities of non-commercial goods in personal effects of passengers or sent in small packages</td>
<td>Uruguay.</td>
<td>1</td>
</tr>
<tr>
<td>General exception based on TRIPS article 30 wording</td>
<td>Egypt</td>
<td>1</td>
</tr>
</tbody>
</table>

[Annex II follows]