



THE NAPLES ROUNDTABLE

Exploring Ways to Strengthen & Improve the Patent System

June 10, 2019

The Honorable Thom Tillis
Chairman, Subcommittee on Intellectual
Property
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

The Honorable Christopher Coons
Ranking Member, Subcommittee
on Intellectual Property
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

Dear Chairman Tillis and Ranking Member Coons:

On behalf of the Naples Roundtable, I write to commend you and your staff on the important work your subcommittee has undertaken on the critical issue of subject-matter eligibility under the U.S. patent laws. Clarifying the scope of what is eligible for patenting under Section 101 of the Patent Act is of fundamental importance to the proper functioning of a balanced patent system.

The current lack of clarity in the wake of the Supreme Court's *Mayo* and *Alice* decisions is untenable and unworkable. Those decisions have put the United States at a competitive disadvantage relative to its foreign trading partners, whose patent laws have far greater clarity with respect to subject-matter eligibility. As a result, other countries' patent systems are better positioned to protect and incentivize R&D in new and emerging fields of technology, such as personalized medicine, artificial intelligence, and quantum computing.

As you work to clarify the scope of patent eligibility, we urge you to also consider additional measures to make clear that patents do not "preempt" innovation. Indeed, U.S. patent law has always contained an implicit "experimental use" exception (a defense to infringement) which allows researchers to study, test, experiment on, and improve upon patented inventions. *See In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 527 (Fed. Cir. 2012) (explaining that "patenting does not deprive the public of the right to experiment with and improve upon the patented subject matter") (citing *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.) ("[I]t could never have been the intention of the legislature to punish a man who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.")). This implicit common-law "experimental use" exception is separate from, and in addition to, the statutory *Bolar* defense that Congress created in 1984 to allow research and testing on patented drugs or veterinary biological products for the



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purpose of developing and submitting information for regulatory approval of generic equivalents. See 35 U.S.C. § 271(e)(1).

Outside of the United States, most other countries have codified an experimental use defense in their patent laws (beyond a *Bolar*-type exception) to allow experimentation on patented inventions in all fields of technology, not just pharmaceuticals. These countries also tend to permit patenting of subject matter more broadly than the United States permits in the wake of *Mayo* and *Alice*.

A detailed study that compares other countries' patent eligibility and experimental use provisions is enclosed. The study was conducted by the amicus committee of the Naples Roundtable. The study's findings suggest that codifying an experimental use defense is a way that countries have addressed concerns over "preemption" and the inhibition of future innovation, while also permitting a broad scope of patent eligibility.

We thank you for your leadership on this important issue and stand ready to provide any assistance to the subcommittee.

About the Naples Roundtable

The Naples Roundtable, Inc. is a 501(c)(3) non-profit organization whose primary mission is to explore ways to improve and strengthen the U.S. patent system. To achieve this goal, the Naples Roundtable supports the advanced study of both national and international intellectual property law and policy. The Naples Roundtable fosters the exchange of ideas and viewpoints among world-leading intellectual property experts and scholars. It also organizes conferences and other public events to promote the development and exchange of ideas to improve and strengthen the U.S. patent system. More information is available at www.thenaplesroundtable.org.

Sincerely yours,

Gary Hoffman
President
Naples Roundtable

Enclosure (1)



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Exploring Ways to Strengthen & Improve the Patent System

PATENT ELIGIBILITY AND EXPERIMENTAL USE: AN INTERNATIONAL COMPARISON

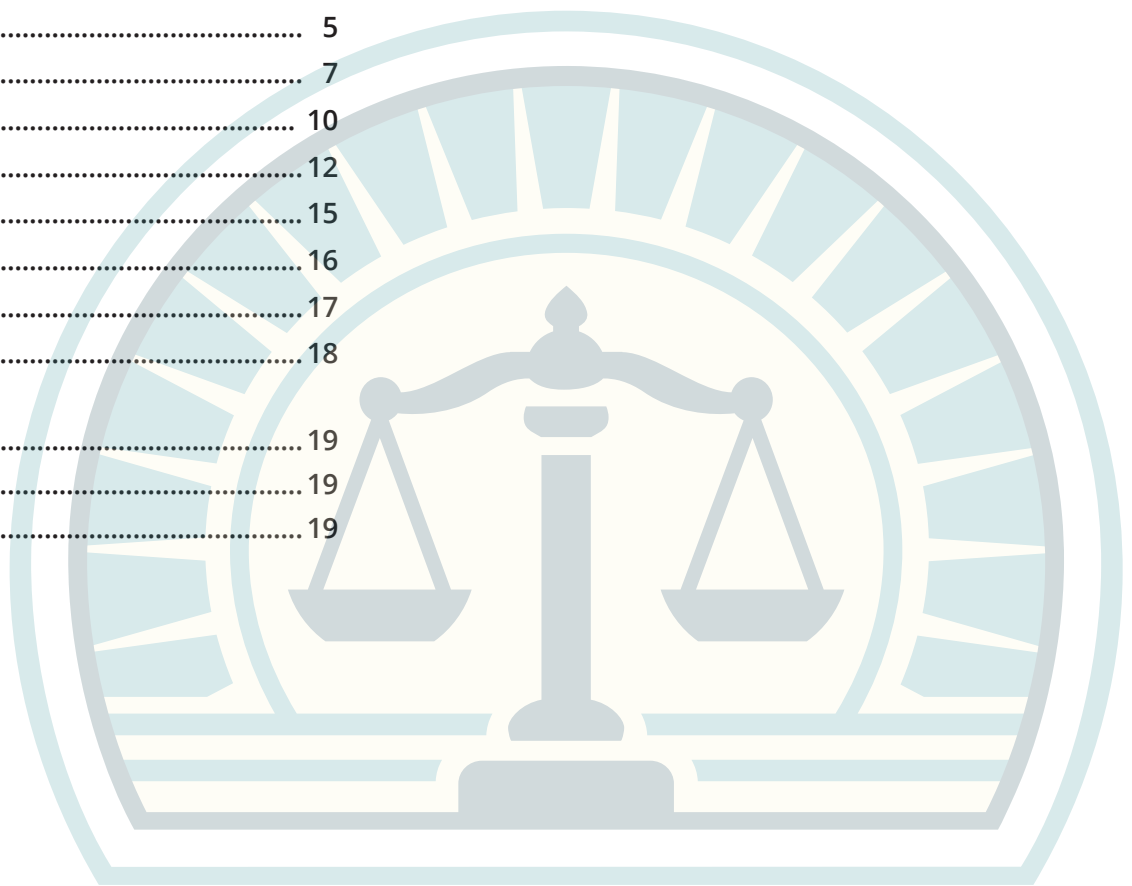
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INTRODUCTION

The Supreme Court of the United States has repeatedly stated that the “risk” or “concern” driving the Court to create judicial exceptions to the otherwise broad scope of patent-eligible subject matter under 35 U.S.C. § 101 is “one of pre-emption.” See *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014) (“We have described the concern that drives this exclusionary principle as one of pre-emption.”); *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (“[W]ithout this exception, there would be considerable danger that the grant of patents would ‘tie up’ the use of such tools and thereby ‘inhibit future innovation premised upon them.’” (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 86 (2012))); *Mayo*, 566 U.S. at 90-91 (2012) (equating the “risk that underlies the law of nature exception” with “the risk that a patent on the law would significantly impede future innovation”); *Bilski v. Kappos*, 561 U.S. 593, 653 (2010) (Stevens, Ginsburg, Breyer, Sotomayor, JJ., concurring) (“Patents can discourage research by impeding the free exchange of information”) (internal quotation marks omitted)).

In other words, the U.S. Supreme Court is worried that allowing too much subject matter to be eligible for patenting under 35 U.S.C. § 101 would impede rather than promote innovation because the resulting patents would prevent scientists and researchers from studying, testing, understanding, and improving upon subject matter that is protected by a 20-year patent.

Outside of the United States, most other countries have codified an “experimental use” defense in their patent laws, allowing any patented invention to be used for the purpose of researching, testing, and improving upon a patented invention. Those same countries also tend to permit patenting of subject matter more broadly under their patent laws than the United States.

In contrast to most other countries, the United States does not have a statutory “experimental use” defense available to defend against any allegation of patent infringement. The United States does have a so-called *Bolar* exception for pharmaceuticals, limited to “the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.” 35 U.S.C. § 271(e)(1). This *Bolar* exception, however, does not extend to all patented technologies, and it does not extend to research whose purpose is other than for the purpose of generating and submitting regulatory information under a Federal law.

Given the U.S. Supreme Court’s concern that broad patent eligibility poses a risk of “pre-emption,” this paper provides an international comparison of the patent eligibility and experimental use defenses codified in the major patent jurisdictions around the world.



SINGAPORE

PATENTABLE ELIGIBILITY



Patentable inventions

13.—(1) Subject to subsection (2), a patentable invention is one that satisfies the following conditions:

- (a) the invention is new;
- (b) it involves an inventive step; and
- (c) it is capable of industrial application.

(2) An invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour is not a patentable invention.

(3) For the purposes of subsection (2), behaviour shall not be regarded as offensive, immoral or anti-social only because it is prohibited by any law in force in Singapore.

Industrial application

16.—(1) Subject to subsection (2), an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

(2) An invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not be taken to be capable of industrial application.

(3) Subsection (2) shall not prevent a product consisting of a substance or composition from being treated as capable of industrial application merely because it is invented for use in any such method.

EXPERIMENTAL USE



Meaning of infringement

66.— (2) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if —

- (a) it is done privately and for purposes which are not commercial;
- (b) it is done for experimental purposes relating to the subject-matter of the invention; . . .

SOURCES

Patents Act (Chapter 221) (Revised Edition 2005, version in force from Oct. 30, 2017), https://sso.agc.gov.sg/Act/PA1994?ViewType=Pdf&_=20181004134539

Winnie Tham & Jessica Waye, AIPPI, Report Q202, Singapore, <https://aippi.org/download/committees/202/GR202singapore.pdf>



UNITED KINGDOM

PATENTABLE ELIGIBILITY



Section 1: Patentable inventions

Patentability.

1. (1) A patent may be granted only for an invention in respect of which the following conditions are satisfied, that is to say -

- (a) the invention is new;
- (b) it involves an inventive step;
- (c) it is capable of industrial application;
- (d) the grant of a patent for it is not excluded by subsections (2) and (3) or section 4A below; and references in this Act to a patentable invention shall be construed accordingly.

(2) It is hereby declared that the following (among other things) are not inventions for the purposes of this Act, that is to say, anything which consists of -

- (a) a discovery, scientific theory or mathematical method;
- (b) a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever;
- (c) a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer;
- (d) the presentation of information; but the foregoing provision shall prevent anything from being treated as an invention for the purposes of this Act only to the extent that a patent or application for a patent relates to that thing as such.

(3) A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality.

(4) For the purposes of subsection (3) above exploitation shall not be regarded as contrary to public policy or morality only because it is prohibited by any law in force in the United Kingdom or any part of it.

(5) The Secretary of State may by order vary the provisions of subsection (2) above for the purpose of maintaining them in conformity with developments in science and technology; and no such order shall be made unless a draft of the order has been laid before, and approved by resolution of, each House of Parliament.

Section 4: Industrial application

Patentability.

1. (1) An invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.

UNITED KINGDOM (con't)

(2) [repealed]

(3) [repealed]

Section 4A: Methods of treatment or diagnosis

Patentability.

4A. (1) A patent shall not be granted for the invention of;

- (a) a method of treatment of the human or animal body by surgery or therapy, or
- (b) a method of diagnosis practised on the human or animal body.

(2) Subsection (1) above does not apply to an invention consisting of a substance or composition for use in any such method.

(3) In the case of an invention consisting of a substance or composition for use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art.

(4) In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art.

Section 76A: Biotechnological inventions

General provisions as to amendment of patents and applications.

76A. (1) Any provision of, or made under, this Act is to have effect in relation to a patent or an application for a patent which concerns a biotechnological invention, subject to the provisions of Schedule A2.

(2) Nothing in this section or Schedule A2 is to be read as affecting the application of any provision in relation to any other kind of patent or application for a patent.

Schedule A2 (section 76A): Biotechnological inventions

Biotechnological inventions

1. An invention shall not be considered unpatentable solely on the ground that it concerns -

- (a) a product consisting of or containing biological material; or
- (b) a process by which biological material is produced, processed or used.

2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.

UNITED KINGDOM (con't)

3. The following are not patentable inventions -

(a) the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene;

(b) processes for cloning human beings;

(c) processes for modifying the germ line genetic identity of human beings;

(d) uses of human embryos for industrial or commercial purposes;

(e) 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;

(f) any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological or other technical process or the product of such a process.

4. Inventions which concern plants or animals may be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.

5. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

6. The industrial application of a sequence or partial sequence of a gene must be disclosed in the patent application as filed.

7. The protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

8. The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

9. The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided for in

UNITED KINGDOM (con't)

paragraph 3(a) above, in which the product is incorporated and in which the genetic information is contained and performs its function.

10. The protection referred to in paragraphs 7, 8 and 9 above shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the proprietor of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation or multiplication.

11. In this Schedule:

“essentially biological process” means a process for the production of animals and plants which consists entirely of natural phenomena such as crossing and selection; “microbiological process” means any process involving or performed upon or resulting in microbiological material; “plant variety” means a plant grouping within a single botanical taxon of the lowest known rank, which grouping can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes; and

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics; and

(c) considered as a unit with regard to its suitability for being propagated unchanged.

EXPERIMENTAL USE



Section 60: Meaning of infringement

Infringement.

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

(a) it is done privately and for purposes which are not commercial;

(b) it is done for experimental purposes relating to the subject-matter of the invention; . . .

SOURCES

Patents Act 1977 (published 25 July 2018, updated August 22, 2018),

<https://www.gov.uk/guidance/the-patent-act-1977>

Jeremy Brown, Alan McBride, Tony Rollins, Trevor Cook, Sebastian Moore, Gareth Morgan, Ian Karet, Alpha Dlubac Indraccolo, Andrew Allan-Jones, Miles Gaythwaite & Sally Mannion, AIPPI, Report Q202, United Kingdom, https://aippi.org/download/committees/202/GR202united_kingdom.pdf



GERMANY

PATENTABLE ELIGIBILITY



Section 1

(1) Patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) Patents shall be granted for inventions within the meaning of subsection (1) even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used. Biological material which is isolated from its natural environment or produced by means of a technical process can also be the subject of an invention even if it previously occurred in nature.

(3) The following in particular shall not be regarded as inventions within the meaning of subsection (1):

1. discoveries, scientific theories and mathematical methods;
2. aesthetic creations;
3. schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
4. presentations of information.

(4) Subsection (3) shall exclude patentability only to the extent to which protection is being sought for the subject-matter or activities referred to as such.

Section 1a

(1) The human body, at the various stages of its formation and development, including germ cells, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention even if the structure of that element is identical to the structure of a natural element.

(3) The industrial application of a sequence or partial sequence of a gene shall be disclosed in the application specifying the function performed by the sequence or partial sequence.

(4) If the invention concerns a sequence or partial sequence of a gene whose structure corresponds to that of a natural sequence or partial sequence of a human gene, the patent claim shall include its use for which industrial application is disclosed pursuant to subsection (3).

Section 2

(1) No patents shall be granted for inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

(2) Patents shall in particular not be granted for

1. processes for cloning human beings;
2. processes for modifying the germ line genetic identity of human beings;

GERMANY (con't)

3. uses of human embryos for industrial or commercial purposes;
4. 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. The relevant provisions of the Embryo Protection Act shall govern the application of nos 1 to 3.

Section 2a

(1) Patents shall not be granted for

1. plant and animal varieties and essentially biological processes for the production of plants and animals and the plants and animals produced exclusively by such processes;
2. methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. This shall not apply to products, in particular to substances or compositions, for use in one of these methods.

(2) Patents can be granted for inventions which concern

1. plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;
2. a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

Section 1a (3) shall apply mutatis mutandis.

(3) For the purposes of this Act,

1. "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system;
2. "microbiological process" means any process involving or performed upon or resulting in microbiological material;
3. "essentially biological process" means a process for the production of plants or animals consisting entirely of natural phenomena such as crossing or selection;
4. "plant variety" means a variety as defined in Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights (OJ L 227 p. 1), as amended.

EXPERIMENTAL USE



Section 11.

The effect of a patent shall not extend to

1. acts done privately and for non-commercial purposes;
2. acts done for experimental purposes relating to the subject-matter of the patented invention; . . .

SOURCES

Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 4 of the Act of 8 October 2017 (Federal Law Gazette I p. 3546), http://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html

Thorsten Bausch, Uli Foerstl, Michael Kompter, Christian Lederer, Andrea Schüssler & Hubert Witte, AIPPI, Report Q202, Germany, https://aippi.org/download/committees/202/GR202germany_en.pdf



FRANCE

PATENTABLE ELIGIBILITY



Article L611-10

(modified by Law n ° 2008-776 of August 4th, 2008 - art. 132)

1. Inventions in all fields of technology shall be patentable for new inventions involving an inventive step and capable of industrial application.

2. The following shall not be considered as inventions within the meaning of the first paragraph of this article:

- (a) Discoveries as well as scientific theories and mathematical methods;
- (b) aesthetic creations;
- (c) Plans, principles and methods in the exercise of intellectual activities, games or the field of economic activities, as well as computer programs;
- (d) Presentations of information.

3. The provisions of paragraph 2 of this Article exclude from patentability the elements enumerated in those provisions only to the extent that the patent application or the patent concerns only one of those elements considered as such.

4. Subject to the provisions of Articles L. 611-16 to L. 611-19 , are patentable under the conditions provided for in 1 the inventions relating to a product made in whole or in part of biological material, or a process for producing , to treat or use biological material.

Biological material is considered to be material that contains genetic information and can be reproduced or reproduced in a biological system.

Article L611-17

(modified by Law No. 2004-800 of August 6, 2004 - art. 17 (V) JORF 7 August 2004)

Inventions whose commercial exploitation would be contrary to the dignity of the human person, public order or morality are not patentable, such annoyance not being able to result from the sole fact that such exploitation is prohibited by a legislative or regulatory provision.

Article L611-18

(created by Law n ° 2004-800 of August 6, 2004 - art. 17 (V) JORF 7 August 2004)

FRANCE (con't)

The human body, at the different stages of its constitution and development, as well as the simple discovery of one of its elements, including the total or partial sequence of a gene, can not constitute patentable inventions.

Only an invention constituting the technical application of a function of an element of the human body can be protected by patent. This protection covers the element of the human body only to the extent necessary for the realization and exploitation of that particular application. This must be concretely and precisely stated in the patent application.

In particular, they are not patentable:

- (a) Methods of cloning human beings;
- (b) methods of modifying the genetic identity of the human being;
- (c) Uses of human embryos for industrial or commercial purposes;
- (d) The total or partial sequences of a gene taken as such.

Article L611-19

(modified by Law n ° 2016-1087 of August 8th, 2016 - art. 9)

I. - The following are not patentable:

1. The animal races;

2 ° Plant varieties as defined in Article 5 of Council Regulation (EC) No 2100/94 of 27 July 1994 establishing a Community plant variety rights scheme;

(3) Essentially biological processes for the production of plants and animals; are considered as such processes that exclusively use natural phenomena such as cross breeding or selection;

3 ° bis Products exclusively obtained by essentially biological processes defined in 3 °, including the elements which constitute these products and the genetic information which they contain;

4 ° Methods of modifying the genetic identity of animals likely to cause in them suffering without substantial medical usefulness for humans or animals, as well as animals resulting from such processes.

II. - Notwithstanding the provisions of I, inventions involving plants or animals are patentable if the technical feasibility of the invention is not limited to a particular plant variety or animal breed.

III. - The provisions of paragraph 3 of I do not affect the patentability of inventions for a technical process, in particular a microbiological process, or a

FRANCE (con't)

product obtained by such a process; is regarded as a microbiological process any process using or producing a biological material or involving an intervention on such a material.

EXPERIMENTAL USE



Article L613-5

The rights conferred by the patent do not extend to:

- (a) acts done privately and for non-commercial purposes;
- (b) experimental acts relating to the subject-matter of the patented invention;
- (c) the preparation of medicines made extemporaneously and by unit in pharmacies, on medical prescription, or acts concerning the medicines thus prepared;
- (d) the studies and tests required to obtain a marketing authorization for a medicinal product and the acts necessary for their completion and for obtaining the authorization;
- (da) the acts necessary to obtain the advertising visa mentioned in Article L. 5122-9 of the Public Health Code;
- (e) Objects intended to be launched into outer space introduced on French territory.

SOURCES

Intellectual Property Code, last modified Dec. 23, 2018, <https://www.legifrance.gouv.fr/affichCode.do?idSectionTA=LEGISCTA000006179052&cidTexte=LEGITEXT000006069414&dateTexte=20190130>
Alain Gallochat, Jean-Christophe Guerrini, Laetitia Benard, Serge Binn, Paule Drouault-Gardrat, Chrystel Lanxade, Laurent Romano & Grégoire Triet, AIPPI, Report Q202, France, <https://aippi.org/download/committees/202/GR202france.pdf>



SOUTH KOREA

PATENTABLE ELIGIBILITY



Article 2 (1)

The term “invention” means the highly advanced creation of a technical idea utilizing the laws of nature.”

Article 29 (1)

An invention having industrial applicability, other than the following, is patentable:

1. An invention publicly known or executed in the Republic of Korea or in a foreign country prior to the filing of a patent application;
2. An invention published in a publication distributed in the Republic of Korea or in a foreign country or an invention disclosed to the public via telecommunications lines prior to the filing of a patent application.

Article 32

(Unpatentable Inventions) Notwithstanding Article 29 (1), no invention that violates public order or sound morals or is likely to harm public health is patentable.

EXPERIMENTAL USE



Article 96-1

- (1) The effects of a patent shall not extend to the following:
1. Execution of a patented invention for the purpose of research or testing (including research and testing for obtaining permission for items of medicines or reporting items of medicines by under the Pharmaceutical Affairs Act or for registering pesticides under the Pesticide Control Act); . . .

SOURCES

Act No. 14112, Mar. 29, 2016, Partial Amendment,
http://www.kipo.go.kr/upload/en/download/PATENT_ACT_2016.pdf
Seong-Ki Kim, AIPI, Report Q202, Republic of Korea,
https://aiippi.org/download/committees/202/GR202rep_of_korea.pdf



JAPAN

PATENTABLE ELIGIBILITY



Article 2

(1) The term “invention” as used in this Act means a highly advanced creation of technical ideas utilizing the laws of nature.

Article 29

(1) A person that invents an invention with industrial applicability may obtain a patent for that invention, unless the invention is as follows:

- (i) an invention that is public knowledge within Japan or in a foreign country prior to the filing of the patent application;
- (ii) an invention that is publicly known to be worked within Japan or in a foreign country prior to the filing of the patent application; or
- (iii) an invention that is described in a distributed publication or made available for public use over telecommunications lines within Japan or in a foreign country prior to the filing of the patent application.

Article 32

An invention that is likely to disrupt public order, corrupt public morals or harm public health may not be patented, notwithstanding Article 29.

EXPERIMENTAL USE



Article 69 (1)

A patent right is not effective against the working of the patented invention for experimental or research purposes.

SOURCES

Act No. 121 of 1959, Amendment of Act. No. 55 of 2015,
<http://www.japaneselawtranslation.go.jp/law/detail/?id=3118&vm=04&re=01>
Japanese Group, AIPII, Report Q202, Japan,
<https://aiippi.org/download/committees/202/GR202japan.pdf>



CHINA

PATENTABLE ELIGIBILITY



Article 2

For the purposes of this Law, invention-creations mean inventions, utility models and designs.

Inventions mean new technical solutions proposed for a product, a process or the improvement thereof.

Utility models mean new technical solutions proposed for the shape and structure of a product, or the combination thereof, which are fit for practical use.

Designs mean, with respect to a product, new designs of the shape, pattern, or the combination thereof, or the combination of the color with shape and pattern, which are rich in an aesthetic appeal and are fit for industrial application.

Article 5

Patent rights shall not be granted for invention-creations that violate the law or social ethics, or harm public interests.

Article 25

Patent rights shall not be granted for any of the following:

- (1) scientific discoveries;
- (2) rules and methods for intellectual activities;
- (3) methods for the diagnosis or treatment of diseases;
- (4) animal or plant varieties;
- (5) substances obtained by means of nuclear transformation; and
- (6) designs that are mainly used for marking the pattern, color or the combination of the two of prints.

The patent right may, in accordance with the provisions of this Law, be granted for the production methods of the products specified in Subparagraph (4) of the preceding paragraph.

EXPERIMENTAL USE



Article 69(4)

The following shall not be deemed to be patent right infringement:

- (4) Any person uses the relevant patent specially for the purpose of scientific research and experimentation; . . .

SOURCES

Third Amendment of the Patent Law of the People's Republic of China, December 27, 2008, <http://english.cnipa.gov.cn/lawpolicy/patentlawsregulations/915574.htm>

Wei Cheng, AIPPI, Report Q202, China, <https://aippi.org/download/committees/202/GR202china.pdf>



UNITED STATES

PATENTABLE ELIGIBILITY



35 U.S.C. 101 Inventions patentable.

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, subject to the conditions and requirements of this title.

Leahy-Smith America Invents Act (AIA), Public Law 112-29, sec. 33(a)

Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

Common Law Exceptions to Patent Eligibility

The U.S. Supreme Court has held that “this provision,” 35 U.S.C. § 101, “contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable.” *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 589 (2013) (internal quotations and brackets omitted). To determine whether a judicial exception applies, the Court has set forth a two-step inquiry. “First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts.” *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2018). Second, “we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application.” *Id.* (internal quotations omitted).

EXPERIMENTAL USE



There is no experimental use defense to patent infringement in the U.S. Code which allows a person to conduct research or testing on any and all patents. The U.S. Supreme Court has never addressed whether there is a judicially-created experimental use defense. The U.S. Court of Appeals for the Federal Circuit, however, has held that any such experimental use defense “is very narrow and strictly limited.” *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (2002). Any such defense is “very narrow and limited to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” *Id.* (internal quotations omitted). “Moreover, use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense.” *Id.*

SOURCES

U.S. Patent Law, 35 U.S.C. §§ 1 et seq. (consolidated as of May 2015), <https://wipolex.wipo.int/en/text/371712>

Amanda Hollis, Henry Blanco-White & Jason Brost, AIPPI, Report Q202, United States of America, <https://aippi.org/download/committees/202/GR202usa.pdf>

CONCLUSION

The major patent jurisdictions around the world have addressed the alleged tension between patent-eligibility and pre-emption by providing in their patent laws an “experimental use” defense. This defense generally protects a researcher from liability for patent infringement if the researcher’s use of the patented invention is done for experimental or research purposes. The United States may wish to consider such a codification as it considers whether to amend the scope of patent eligibility under 35 U.S.C. § 101.

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