Some best and worst policies and practices regarding limitations and exceptions to patent rights

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Research exception

Some statutory research exceptions

Germany. The effects of a patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.

Vietnam: Using inventions for purpose of evaluation, analysis, research, teaching, testing, trial production.

Switzerland: acts undertaken for experimental and research purposes in order to obtain knowledge on the subject of the invention, including its possible uses; in particular all scientific research concerning the subject of the invention shall be permitted.

USA’s more narrow exception

- In general, Courts have held that experimentation is not a defense to infringement if it creates a benefit for the accused infringer.
- There is a statutory exception related to the experimental use of a patented invention by parties to collect regulatory approval data for medical devices or drugs.
- Publicly funded research typically includes a mandatory royalty free right for use by or for the federal government, which has been used to protect researchers, particularly on biomedical research.
- State sovereign immunity for state universities are shielded from patent infringement suits.

Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002) narrowed the US research exception

A 1861 court decision had earlier referred to the common law exception as applying narrowly to "an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement." *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861). Several subsequent court decisions rejected the experimental use defense to infringement claims, for example,finding that an "economically feasible commercial application" of patented technology was not "strictly intellectual experimentation". *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 633 (1990).

In 1984, in a dispute involving involving patents on the drug flurazepam, a court held that the experimental use defense for the use of a patented drug to perform tests necessary to gain FDA regulatory approval for a generic competitor. *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984),

Congress responded by creating a specific new statutory exception for this narrow propose. Section 35 USC 271(e)(1 stated 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 or veterinary biological products."

In 2002, a decision of the Court of Appeals in in Madey v. Duke University, 307 F.3d 1351, 1362 (Fed. Cir. 2002), limited the scope of the research exemption, by finding that a non profit entity, in this case Duke University, could not use the common law defense when it was using the invention "to increase the status of the institution and lure lucrative research grants, students and faculty."

USPTO RFC on the Experimental Use Exceptions

- “Many European nations, including Germany,[20] the UK,[21] France,[22] Spain,[23] Italy,[24] Switzerland,[25] and the Netherlands [26] have implemented a statutory experimental use exception for otherwise infringing uses. Although the precise application of each of these national exceptions varies based on interpretation in national courts,[27] they are each broader than the U.S. common law exception as they apply to any experimental purpose.”

  89 FR 53963

Exhaustion of patent rights (first sale doctrine)

TRIPS provides considerable flexibility for policies on exhaustion

Article 6 – Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

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(Article 3 is National Treatment and Article 4 is Most-Favoured-Nation Treatment)

Two US Supreme Court cases made it clear that the United States has international exhaustion of patents and copyrights

Patents: *Products v. Lexmark Int'l*, 137 S.Ct. 1523 (2017);

A United States patent entitles the patent holder to "exclude others from making, using, offering for sale, or selling [its] invention throughout the United States or importing the invention into the United States." 35 U. S. C. §154(a). Whoever engages in one of these acts "without authority" from the patentee may face liability for patent infringement. §271(a). When a patentee sells one of its products, however, the patentee can no longer control that item through the patent laws—its patent rights are said to "exhaust."

Copyright: *Kirtsaeng v. John Wiley & Sons*, 568 U.S. 519 (2013):

The "exclusive rights" that a copyright owner has "to distribute copies . . . of [a] copyrighted work," 17 U. S. C. §106(3), are qualified by the application of several limitations set out in §§107 through 122, including the "first sale" doctrine, which provides that "the owner of a particular copy or phonorecord lawfully made under this title . . . is entitled, without the authority of the copyright owner, to sell or otherwise dispose of the possession of that copy or phonorecord," §109(a).

UK, regional exhaustion of patent IP rights

The UK's current exhaustion regime ensures that once a good has been legitimately placed on the market in either the UK or the European Economic Area ("EEA"), the relevant IP rights in that good are "exhausted" in the UK. After this, the rights holder cannot use their IP rights to control the distribution of the good (e.g., prevent the import of the good from the EEA into the UK). This principle does not apply to counterfeit goods or purely digital content. It also underpins the rules on the parallel importation of goods into the UK, which is the movement of genuine physical goods that are first sold outside of the UK, bought by secondary market actors, and imported into the UK's territory.

. . . The purpose of these Regulations is to ensure the continuity of the UK's exhaustion regime at the end of 2023 without any substantial changes to this policy area. These Regulations therefore do not affect the government's ability to amend the territorial extent of the UK's exhaustion regime in the future

The European Union, Agreement on a Unified Patent Court

Article 29

Exhaustion of the rights conferred by a European patent

The rights conferred by a European patent shall not extend to acts concerning a product covered by that patent after that product has been placed on the market in the European Union by, or with the consent of, the patent proprietor, unless there are legitimate grounds for the patent proprietor to oppose further commercialisation of the product.

Marco M. Aleman's 2011 report on exhaustion

Regional Seminar on the Effective Implementation and Use of Several Patent-Related Flexibilities
Bangkok, Thailand
March 29 to 31, 2011

Countries analyzed: Exhaustion

Region	National	Regional	International
Africa	12	16	2
Central and Latin America	9	0	14
Asia and Oceania	13	0	8
Europe	5	31	1
OECD countries	2	16	0

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

SCP/34/3 Draft Reference Document on the Exception Regarding the Exhaustion of Patent Rights, AUGUST 18, 2022

On page 14, WIPO lists 30 countries as having regimes of national exhaustion:

Albania, Barbados, Belarus, Belize, Bhutan, Bosnia and Herzegovina, Brazil, Dominica, El Salvador, Eswatini, Ethiopia, Gambia, Iran (Islamic Republic of), Kazakhstan, Madagascar, Mexico, Morocco, Mozambique, Nigeria, Papua New Guinea, Republic of Moldova, Saint Kitts and Nevis, San Marino, Sao Tome and Principe, Serbia, South Sudan, Sudan, Tajikistan, Trinidad and Tobago, United Republic of Tanzania.

For international exhaustion, the number is 59 (not including South Africa).

Antigua and Barbuda, Argentina, Armenia, Benin*, Bolivia× , Botswana, Brunei Darussalam, Burkina Faso*, Burundi, Cambodia, Cameroon*, Central African Republic*, Chad*, Chile, China, Colombia× , Comoros*, Congo*, Costa Rica, Côte d'Ivoire*, Cuba, Dominican Republic, Ecuador× , Equatorial Guinea*, Gabon*, Ghana, Guatemala, Guinea*, Guinea Bissau*, Honduras, India, Jamaica, Jordan, Kenya, Kyrgyzstan, Liberia, Mali*, Mauritania*, Mauritius, Namibia, Nicaragua, Niger*, Pakistan, Paraguay, Peru× , Samoa, Senegal*, Seychelles, Sierra Leone, Thailand, Togo*, Tonga, Tunisia, Türkiye, United States of America, Uruguay, Viet Nam, Zambia, Zimbabwe.

Best practice on exhaustion

In KEI's view, the best practice on exhaustion is a general policy of international exhaustion for most goods, but with the possibility of limited exceptions.

In particular, countries should consider limited and nuanced exceptions for international exhausions for some products for which lower prices in countries with lower incomes are appropriate, particularly for drugs and other medical productions, copyrighted education materials, and some entertainment goods.

For goods including medicines, limits on exhaustion should subject to exceptions to the exceptions, to address cases of abuses of patent rights or shortages.

Non-voluntary use of patents - limitations on Remedies for infringement

Part III of TRIPS, Article 44 on Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, inter alia to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006)

According to well-established principles of equity, a plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate:

(1) that it has suffered an irreparable injury;

(2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury;

(3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and

(4) that the public interest would not be disserved by a permanent injunction.

Every patent permanent injunction case in the US is now a potential compulsory licensing case

Decisions are made by Courts.

Ongoing, or “running” royalties are set by juries or judges.

Unlike Article 31 compulsory licenses, there are no requirements for prior negotiations with patent holders.

There are no restrictions on exports or imports. (no TRIPS 31.f, 31bis or June 17, 2022 conditions attached)

The United States’ non voluntary use of patents by or for the government under FAR 52.227-1

Uses inventions “by or for” the US government

28 USC §1498 . Patent and copyright cases

(a) Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . .

For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.

The Federal Acquisition Regulation (FAR) is the primary regulation for use by all executive agencies in their acquisition of supplies and services with appropriated funds. The FAR also contains standard solicitation provisions and contract clauses and the various agency FAR supplements.

52.227-1 Authorization and Consent (June 2020)

(a) The Government authorizes and consents to all use and manufacture, in performing this contract or any subcontract at any tier, of any invention described in and covered by a United States patent-

(1) Embodied in the structure or composition of any article the delivery of which is accepted by the Government under this contract; or

(2) Used in machinery, tools, or methods whose use necessarily results from compliance by the Contractor or a subcontractor with (i) specifications or written provisions forming a part of this contract or (ii) specific written instructions given by the Contracting Officer directing the manner of performance. the entire liability to the Government for infringement of a United States patent shall be determined solely by the provisions of the indemnity clause, if any, included in this contract or any subcontract hereunder (including any lower-tier subcontract), and the Government assumes liability for all other infringement to the extent of the authorization and consent hereinabove granted.

(b) The Contractor shall include the substance of this clause, including this paragraph (b), in all subcontracts that are expected to exceed the simplified acquisition threshold, as defined in Federal Acquisition Regulation (FAR) 2.101 on the date of subcontract award. However, omission of this clause from any subcontract, including those at or below the simplified acquisition threshold, as defined in FAR 2.101 on the date of subcontract award, does not affect this authorization and consent.

Including FAR 52.227-1 in a contract

The text of the clause can be included in a contract, or, more commonly, included by reference

Examples

KEI collection of contracts with FAR 52.227-1 (link)

The Biologics Price Competition and Innovation Act

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) was enacted as part of the Patient Protection and Affordable Care Act (Pub. L. 111-148) on March 23, 2010. The BPCI Act amended the PHS Act and created an abbreviated licensure pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product.

The Act describes certain procedures for exchanging patent information and resolving patent disputes between an applicant and the holder of the BLA reference product.

Failures to timely disclose and/or litigate patents on reference biologic drugs result in either a compulsory license on the patents or an elimination of any remedy for infringement as it relates to the biosimilar product

35 USC 271(e)(6)(A-C), Infringement of patent

(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product—

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

The BPCIA disclosure provisions

Requires timely and constructive disclosure and resolution of patent landscapes for medical inventions as an obligation on rights holders.

Could be implemented with greater obligations regarding enablement regarding the biologic product (more know-how), and with more timely transparency.

US exception for compounding when Drugs are on FDA's Drug Shortages List

The U.S. provides an exception for the compounding or products that are on the FDA drug shortages list. The exception extends to patents and regulatory exclusivities.

This exception is currently in use for GPL-1 weight loss drugs.

Current shortage status of GLP-1 products (as of October 02, 2024):

- Tirzepatide injection: Shortage resolved.
- Dulaglutide injection: In shortage.
- Semaglutide injection: In shortage. Manufacturer has reported all but one of the presentations are available.
- Liraglutide injection: In shortage. Manufacturer has reported 2 presentations are available, and three have limited availability.

US: 19 U.S.C. 1337 - Unfair practices in import trade

(e) Exclusion of articles from entry during investigation except under bond; procedures applicable; preliminary relief

(1) If, during the course of an investigation under this section, the Commission determines that there is reason to believe that there is a violation of this section, it may direct that the articles concerned, imported by any person with respect to whom there is reason to believe that such person is violating this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.

Technology transfer

Technology transfer in US competition cases

2024:3 KEI Briefing Note:

What measures do US competition authorities refer to in technology transfer mandates.

2024:2 KEI Briefing Note:

Examples of US competition cases that mandate transfer of technology and know-how.

European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC)

816/2006 (COM(2023)0224 – C9-0151/2023 – 2023/0129(COD))

(32a) Where appropriate, the Commission should oblige the rights-holder to disclose the trade secrets which are strictly necessary in order to achieve the purpose of the Union compulsory licence. In such cases, rights holders should receive an adequate remuneration. It is possible that a detailed description of how to carry out the invention might not be sufficient and complete enough to enable the licensee to efficiently use that invention. This could encompass, without being exhaustively limited to, the comprehensive transfer of necessary technology, expertise, data, samples, and reference products essential for production and obtaining market authorisation in collaboration with the licensee, taking into account both the rights-holder and the licensee's interests. In cases where that additional information and know-how is necessary, some of which is an undisclosed trade secret, the disclosure of that necessary trade secret, with a view to only achieving the purpose of exercising the Union compulsory licence pursuant to this Regulation, should be considered to be lawful within the meaning of Article 3(2) and Article 5 of Directive (EU) 2016/943 of the European Parliament and the Council. . . .

(32b) This Regulation should guarantee that the Commission has the authority to oblige rights-holders to provide all necessary information to facilitate the rapid and efficient production of critical crisis-related products, such as pharmaceuticals and other health-related items. This information should encompass details about know-how, particularly when it is essential for the effective implementation of compulsory licensing. While patent licensing alone might suffice to enable other manufacturers to quickly produce simple pharmaceuticals, in case of more intricate pharmaceutical products, such as vaccines during a pandemic, it is often insufficient. Where it is essential for the implementation of the compulsory licence, an alternative producer will also require access to know-how.

Treatment of a human

Article 27(3)(a) of TRIPS:

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

USA, 35 USC § 287. Limitation on damages and other remedies . . ..

35 USC 287(c)

(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(2) For the purposes of this subsection:

(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.

Spain’s use of Hospital exception for CAR T treatments

Politico’s Morning Health Care, September 25, 2024

"SPAIN WILL CHASE THE ‘IMPOSSIBLE’ ON ADVANCED THERAPIES: Spain wants to expand access to advanced therapies with a new version of a plan that has seen 1,406 patients treated with CAR-T therapies over the last six years, Health Minister Mónica García said on Tuesday. A committee will develop a new version of the advanced therapies plan, before the end of the year, which will expand access and include new therapies “that will undoubtedly change the lives of many more patients,” García said. “There is still much to achieve and we are going to make the impossible possible.”

Small print: Spain’s EU-leading, hospital-made advanced therapies might however be under threat — if right-leaning negotiators get their way in the pharma legislation. The European People’s Party rapporteur wanted to significantly restrict this so-called hospital exemption to make cell and gene therapies, while the Commission wanted to standardize the process."

Thank you

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