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Pharmaceutical IP and competition law in the United States: overview

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PATENTS

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

Patent laws are generally codified in Title 35 of the US Code. The laws, regulations, policies, and procedures that apply to the patent process are available at *www.uspto.gov/patents/law/index.jsp*.

Any of the following can be patented, if it is new and useful:

- Process.
- Machine.
- Manufacture.
- Composition of matter.
- An improvement of any of the above.

The requirements to obtain a patent include:

- Novelty.
- Non-obviousness.
- Utility.

Novelty and non-obviousness are assessed based on the prior art at the time of filing a patent application and the level of skill of ordinary skilled artisans.

Scope of protection

Patent protection can be applied to practically every man-made product and the processes for making products, provided those products and processes satisfy the legal requirements. Pharmaceutical and medicinal products generally fall within the scope of patentable subject matters. The following cannot be patented:

- Laws of nature.
- Physical phenomena.
- Abstract ideas.
- Mere ideas or suggestions.
- Literary, dramatic, musical or artistic works.
- Non-useful inventions.
- Inventions that are offensive to public morality.

First-Inventor-to-File

On 16 September 2011, the Leahy-Smith America Invents Act (AIA) was enacted (*Public Law 112-29*). The AIA makes significant changes to the U.S. patent system, including changing from the prior "first-to-invent" system to a "first-inventor-to-file" system for patents filed on or after 16 March 2013 (*section 3, AIA, 35 USC § 100*). The AIA eliminates interference proceedings that formerly determined priority as between applications claiming the same invention. Under the new system, priority is determined by filing date. The AIA allows for administrative "derivation proceedings" to ensure that the patent-holder is actually the inventor.

2. How is a patent obtained?

Application and guidance

Patent applications can be filed electronically with the US Patent and Trademark Office (USPTO) through the Electronic Filing System (EFS-Web) at *www.uspto.gov/patents/process/file/efs/index.jsp*. The USPTO website provides guidance and resources to assist with the patent application process. The USPTO fee schedule can be found at *www.uspto.gov/about/offices/cfo/finance/fees.jsp*.

Process and timing

The timetable to issue a patent can vary a great deal, but the average patent application time is currently about 29 months. Once a patent application is filed, it undergoes a USPTO examination process, which includes formal reviews and a substantive examination of the application. The status of a patent application and associated documents can be accessed through the USPTO's Patent Application Information Retrieval (PAIR) System. Rejected applications can be appealed to the Board of Appeals and Inferences and even to the courts (for further details of the application process, see *35 USC §§ 111 and 112*).

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

A patent's duration is usually 20 years from the date of original filing (*35 USC § 154(a)(2)*), subject to payment of maintenance fees. Once a patent expires, the inventor loses exclusive rights, and the patent cannot be renewed.

Extending protection

In certain circumstances, the duration of patent protection can be extended or adjusted. For example, in some cases where delay is due to the USPTO or FDA approval process, a patent's term can be extended or adjusted to offset the delay.

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4. How can a patent be revoked?

Patent protection can cease due to various reasons, including the:

- Patent can be held unenforceable.
- Patent can be held invalid.
- Owner may not comply with required post-grant activities.

A patent can be held unenforceable if those who sought and participated in its prosecution are found to have engaged in inequitable conduct before the USPTO. Invalidity can stem from a post-grant issue by showing (to a court or even the USPTO by way of re-examination):

- Lack of novelty.
- Obviousness.
- Lack of enablement.
- Lack of written description (the patent lacks sufficient disclosure to show that the inventors had possession of their invention at the time of filing).

If an owner does not pay its required maintenance fees or fails to respond to a re-examination request, the patent may be cancelled. Laches can also prevent patent rights enforcement, such as when a patent owner knows about infringing activity but waits a long period of time to enforce its rights.

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

A patent is infringed on the unauthorised making, using, importing into the US, offering for sale or selling of any patented invention during the term of the patent.

Claim and remedies

If a patent is infringed, the patent holder can sue in federal court for damages and also seek an injunction to stop the infringing activity (for the patent infringement and remedy process, see *35 USC §§ 271-297*).

6. Are there non-patent barriers to competition to protect medicinal products?

Drug manufacturers receive five years of exclusivity for new chemical entities and three years of exclusivity for new indications. The BPCIA provides for a 12-year exclusivity period for biological products (*42 USC § 262*). Marketing exclusivity is extended in some circumstances. For example, FDAMA amended the FDCA to provide for an additional six months of exclusivity for drugs studied for use in a pediatric population (*21 USC § 355a(b)*). The GAIN Act, enacted as Title VIII of FDASIA, provides for an additional five years of exclusivity for drugs designated as QIDPs (*21 USC § 355f*).

TRADE MARKS

7. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

A trade mark must be capable of distinguishing goods or services from those of another, and it must be in use (and in interstate commerce for federal protection). A trade mark application can be submitted in three situations:

- The applicant has already begun using a mark in commerce.
- The applicant has not yet used the mark but intends (in good faith) to use it in commerce.
- There is a foreign applicant who has an application or registration in another country (under certain international agreements).

While trade mark law is regulated by federal and state law, federal law provides the primary source of trade mark law (*Trademark Rules of Practice, 37 CFR Part 2 and Lanham Act, 15 USC § 1051, et seq.*).

Scope of protection

A trade mark typically protects brand names and logos used on goods and services. Trade mark law generally applies to pharmaceutical and medicinal products in the same way it does to other products. The USPTO may refuse a trade mark registration for a number of reasons, including that the mark is:

- Likely to cause confusion with an existing mark.
- Merely descriptive.
- Immoral or scandalous.
- A surname.
- A geographic term.

8. How is a trade mark registered?

Application and guidance

Trade mark applications can be filed electronically with the USPTO through the Trademark Electronic Application System (TEAS) at *www.uspto.gov/teas/index.html*. The USPTO website provides guidance and resources to assist with the trade mark application process. The USPTO fee schedule can be found at *www.uspto.gov/about/offices/cfo/finance/fees.jsp*.

Process and timing

If an application is submitted online through the TEAS, the applicant receives an initial summary and assigned serial number almost immediately. The total time for an application to be processed can vary from one year to several years. The application timing depends on the basis for filing and the legal issues that may arise. Current status information on trade mark applications is available through the Trademark Status and Document Retrieval (TSDR) database at *http://tsdr.uspto.gov/*.

9. How long does trade mark protection typically last?

The initial and extendable duration of a trade mark registration is ten years.

A trade mark holder must file a Declaration of Continued Use or Excusable Nonuse (§8 Declaration) during the fifth or sixth year after the registration date or within the subsequent six-month grace period (*15 USC § 1058*). Failure to file a §8 Declaration results in cancellation of the trade mark registration.

During the ninth or tenth year after the registration date, and before the end of every additional ten-year period, the holder must file a combined §8 Declaration and §9 Application for Renewal (*15 USC § 1059*). The combined declaration can also be filed within a six-month grace period after then. Failure to make these required filings will result in cancellation of the registration.

A trade mark can last indefinitely provided the owner (*15 USC §§ 1058-59*):

- Continues to use the trade mark in connection with all of the goods or services identified in its application.
- Renews its registration.
- Pays the applicable fees.

10. How can a trade mark be revoked?

A trade mark's registration can be cancelled in any of the following circumstances (*15 USC § 1064*):

- The trade mark becomes a generic name for the goods or services.
- The trade mark has been abandoned.
- Registration was obtained fraudulently.
- The trade mark is used to misrepresent the source of the goods or services with which it is connected.
- A trade mark is cancelled by an opponent (subject to a quasi-judicial cancellation proceeding administered by the USPTO).

11. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

The use of a registered trade mark in connection with the sale of goods constitutes infringement if it is likely to cause consumer confusion as to the source of those goods or as to the sponsorship or approval of such goods. In deciding whether consumers are likely to be confused, the courts typically look to a number of factors, including the:

- Strength of the mark.
- Proximity of the goods.
- Similarity of the marks.
- Evidence of actual confusion.
- Similarity of marketing channels used.
- Degree of caution exercised by the typical buyer.
- Defendant's intent.

Claim and remedies

Enforcement of a trade mark is achieved by bringing an action for trade mark infringement in civil court. The action can be based on a registered trade mark or on common law rights in a trade mark. The remedies available for trade mark infringement include:

- Injunctive relief.
- Monetary relief.
- Treble damages.
- Attorneys' fees.
- Destruction of infringing items.

12. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

FDA works with industry and other law enforcement agencies, such as the Drug Enforcement Administration (DEA), the Customs and Border Protection and US Immigration and Customs Enforcement (in the US Department of Homeland Security), and US Postal Service inspectors to secure the increasingly complex global drug supply chain.

FDA employs a risk-based strategy in its enforcement efforts to identify drugs most likely to be counterfeited, contaminated, or adulterated and to target shipments for additional sampling and testing. FDA is also active in the World Health Organisation's International Medical Products Anti-Counterfeiting Task Force (IMPACT), a public/private effort to develop regulatory, legislative, enforcement, communication, and technological tools to combat counterfeit drugs around the world. Additionally, FDA works with pharmaceutical manufacturers, wholesale distributors, retailers, and other dispensers to identify and prevent counterfeit drugs (*see www.fda.gov/drugs/drugsafety/ucm180899.htm*).

Companies whose products have been counterfeited have certain rights as crime victims when those crimes are prosecuted in US federal district courts, according to the Crime Victims' Rights Act of 2004 (CVRA) (*Pub. L. No. 108-405, 118 Stat. 2260*). Among those rights are the right not to be excluded from public court proceedings, the right to be heard at certain criminal proceedings, and, significantly, the right to full and timely restitution as provided by law (*see 18 U.S.C. § 3771(a)*). The CVRA gives crime victims the right to restitution "as provided by law" and provides victims with a means of enforcing that right. Other statutes determine whether a victim is entitled to restitution in a particular case. Restitution may be either mandatory or within the discretion of the sentencing judge (*see 18 U.S.C. §§ 3663 and 3663A*). A court must order restitution for victims of certain property crimes where the victim has suffered a pecuniary loss (*see 18 U.S.C. § 3663A*). In addition, restitution is mandatory when a criminal defendant is convicted of trafficking in counterfeit goods or services under 18 U.S.C. § 2320 (*see 18 U.S.C. § 2323(c)*). Companies victimised by counterfeiters can recover their lost profits or sales in addition to expenses incurred in assisting with the criminal investigation. Working with federal prosecutors in counterfeiting cases is one step companies can take to both deter counterfeiting and recover their losses from the counterfeiters' crimes.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in the United States: overview*.

IP and competition law issues

13. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The Federal Trade Commission (FTC) is the agency charged with enforcing competition law (anti-trust law) in the US (*see www.ftc.gov*). Within the FTC, the Bureau of Competition enforces US anti-trust laws. Generally, it seeks to prevent attempts to prevent monopolies and activities that reduce competition and drive prices higher. The FTC's authority in this area derives from the Federal Trade Commission Act 1914 (*15 U.S.C. §§ 41 to 58*) (FTC Act), and the Clayton Antitrust Act 1914 (*15 U.S. C. §§ 12–27 and 29 U.S.C. §§ 52 to 53*).

Some intentional anti-competitive conduct violates US federal criminal law. The US Department of Justice's Antitrust Division enforces US anti-trust laws in conjunction with the FTC's Bureau of Competition (*see www.justice.gov/atr*). The Antitrust Division handles criminal anti-trust matters (*see also Question 16*).

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context

Companies spend billions in research and development efforts to bring a drug to market, and patent exclusivity is the only effective way to protect and receive a return on their investment. The lengthy time period between patent filing and placing a drug on the market means that the manufacturer has a shorter period of patent exclusivity than is the case for other industries. This problem has been addressed by the Hatch-Waxman Act, that allows an applicant to apply for an extension of patent term to compensate for the inability to market inventions due to safety and efficacy regulation (*see Question 15*).

15. Are there competition issues associated with the generic entry of pharmaceuticals in your jurisdiction?

Generic competition has increased in the US prescription drug industry and become a major source of healthcare cost savings. One key event was the passage of the Drug Price Competition and Patent Term Restoration Act 1984 (*Pub. L. No. 98-417, 98 Stat. 1585 (24 September 1984)*), better known as the Hatch-Waxman Act. This Act significantly reduced the cost and time for entry for generic drugs by establishing the Abbreviated New Drug Application (ANDA) procedure. Generic drug manufacturers must only establish that their products are bioequivalent to the branded product. The law established a research exemption so that generic manufacturers could perform bioequivalence testing and receive conditional FDA approval before the expiration of the branded product's patent. The law also provided brand name firms with the opportunity for patent term extension to compensate for time lost during the clinical testing and regulatory approval stages.

The Hatch-Waxman Act encourages the filing of ANDAs by granting the first filer the opportunity to market a generic version of the drug for 180 days without competition from any other generic manufacturer. This 180-day exclusivity period can be worth millions to the generic drug manufacturer. The Act provides a framework and incentivises collusive settlement agreements among the NDA holder and generic manufacturers.

16. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

Name brand drug manufacturers invest billions into research and development to bring their products to market. Accordingly, they have an interest in recouping their massive investment.

Some manufacturers have entered into agreements with manufacturers of generic drugs to delay bringing generics to market once patent protection for the name-brand drugs runs out. Not infrequently, a generic manufacturer sues the name brand manufacturer to challenge its patent rights. The companies then enter into a settlement agreement under which the name brand manufacturer pays a sum of money to the generic manufacturer and the introduction of the generic is delayed. These "pay for delay" patent settlements effectively block all other generic drug competition for a growing number of branded drugs.

In *Federal Trade Commission v. Actavis* (*133 S. Ct. 1310 (2013)*), the US Supreme Court rejected the notion that these agreements are *per se* illegal but held that the agreements could violate anti-trust laws in at least some circumstances, depending on a number of factors, including the size of the payment to the generic manufacturer. Under this ruling, the Federal Trade Commission (FTC) can bring anti-trust actions regarding these agreements, which is expected to deter their use.

17. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

US trade mark law governing the parallel importation of genuine goods is found in sections 42 and 32 of the Lanham Act (*see 15 U.S.C. §§ 1114, 1124 (1994)*). Under the Lanham Act, the claimant has the burden of proof to show the goods are not "genuine" and therefore likely to cause consumer confusion.

Trade mark owners also receive protection under section 526 of the Tariff Act (*see The Tariff Act 1930, 15 U.S.C. § 1526 (1994)*). The Tariff Act prohibits the importation of goods under a trade mark owned by a US citizen without the written consent of the trade mark holder.

An exception to the general prohibition of parallel imports is the "common-control exception", which allows the importation of trade marked goods without the consent of the domestic trade mark holder "where that mark holder is either a parent, a subsidiary of, or held in common ownership with a foreign manufacturer" (*Kmart v. Cartier, 486 U.S. 281, 282–83 (1988)*). See also 19 C.F.R. § 133.21(c)(2) (codifying common control exception). The common-control exception only applies where imported goods are identical to those on the US market. If goods are imported by an entity that has a corporate relationship with a domestic trade mark holder, the burden is on the trade mark holder to prove the goods in question are materially different from those on the US market. A parallel importer who violates the Tariff Act can be subject to damages and profits and may be required to either export or destroy the merchandise (*see 19 C.F.R. § 133*).

18. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a licence made enforceable?

There is no requirement for patent or trade mark licence agreements to be approved by a government or regulatory body. There is no governmental or regulatory approval required for royalties payable to a foreign licensor as a result of a patent or trade mark licence agreement.

Subject to the terms of the licensing agreement, a licensee can enforce its rights under the licensing agreement against third parties.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in the United States: overview*.

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Recent transactions

- Regularly defends pharmaceutical and medical device companies in complex litigation, including product liability and commercial matters.
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