Pharmaceutical IP and competition law in The Netherlands: 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

A Dutch patent can be obtained under the Dutch Patent Act 1995, the European Patent Convention and the Patent Cooperation Treaty. Article 21(1) of the Patent Act complies with Article 52(1) of the European Patent Convention, stating that a patent can only be granted to those inventions which are:

- New.
- Involve an inventive step.
- Capable of industrial application.

Scope of protection

According to the Patent Act, inventions related to medicinal products, particularly substances or compositions, are regarded as being capable of industrial application, and therefore can obtain patent protection if they meet the legal requirements.

Methods for treatment of the human body or animal body whether through surgery or medical treatment and diagnostic methods practised on the human or animal body are not regarded as inventions that are susceptible of industrial application. This provision does not apply to products, particularly substances or compositions, for use in any of these methods.

2. How is a patent obtained?

Application and guidance

The Netherlands Patent Office is the Dutch authority responsible for processing patent applications and granting patents.


Process and timing

Within 13 months of the submission of a complete patent application or on the first priority date (if applicable), the applicant can request the Patent Office to conduct a search concerning the state of the art of the subject matter of the patent application (Article 32, DPA).

As soon as possible after the expiration of an 18 month time period (starting from the application date or the first priority date, if applicable) the Patent Office will register the patent application in the patent register. The registration of the patent application can happen at an earlier date if the applicant so requests (Article 31, Patent Act).

If the applicant does not request a search of the state of the art within the allotted time or he informs the Patent Office in writing that he will not make such a request, the patent will be granted as soon as the patent application is registered in the patent register (Article 33(I), Patent Act).

If the applicant requests a search of the state of the art, the Patent Office will grant the patent as soon as the patent application has been entered in the register, but no earlier than either (Article 36(I), Patent Act):

- Two months, if there is a time limit extension for a patent division or amendment.
- Four months from the date of notifying the applicant about the results of the search of the state of the art.

Dutch law does not include opposition proceedings against the grant of a patent.

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

Duration and renewal

A Dutch patent is valid for 20 years, starting from the patent application date (Article 36(5), Patent Act). Renewal of a patent is not possible under Dutch law.

Extending protection

Supplementary protection certificates (SPCs) for medicinal products can be granted for a period not exceeding five years, as regulated under Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products (Consolidated SPC Regulation).

Medicinal products that have been authorised for the paediatric population and that have been granted an SPC can enjoy an additional six months of protection (Regulation (EC) 1901/2006 on medicinal products for paediatric use (Paediatric Medicinal Products Regulation)).

An application for a Dutch SPC is made to the Patent Office with proof of payment of the appropriate fee.
4. How can a patent be revoked?

A Dutch patent can be revoked by a court decision. The District Court of the Hague has exclusive jurisdiction in the first instance for the invalidation of a patent (Article 80(1)(a), Patent Act). The court will invalidate a Dutch patent if its (Article 75(1), Patent Act):

- Subject matter is not patentable because it lacks novelty, inventive step, is not capable of industrial application, or its publication or exploitation would be contrary to public order or morality.
- Specification does not contain a description of the invention.
- Subject matter extends beyond the scope of the patent application as filed.
- Scope of protection is extended after the grant.
- Owner is not entitled to the patent.

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

Conditions for infringement

An owner of a Dutch patent is entitled to exclusive rights over the patent, such as (Article 53(1), Patent Act):

- Making, using, putting on the market or reselling, hiring out or delivering the patent product or the process, or otherwise dealing with it in or for his business.
- Offering, importing or stocking it for any of these purposes.

Patent infringement occurs if a third party conducts any of these acts in relation to the patented product or process, without the permission of the patent owner.

Third parties can benefit from experimental use and regulatory approval exemptions, under Articles 53(3) and 53(4) of the Patent Act. According to Dutch case law, the term experimental use refers to research which is any of the following:

- Aimed at realising a purpose that complies with the intent of patent law, such as research and manufacturing of pharmaceutical substances/products to find a second medical use (Boehringer v Kirin Aman; (1995, NJ 1995/103)).

The new Article 10(6) of the Code for Human Medicines Directive has been implemented under Article 53(4) of the Patent Act. This brings under the research exemption only those tests and trials performed to authorise medicinal products as generic medicinal products.

Any third party conduct which, without the patent owner’s permission, extends beyond the limits set by the Patent Act and the relevant case law, will give rise to patent infringement. Using a patent as a research tool would also result in patent infringement under Dutch law.

Claim and remedies

The Hague District Court has exclusive jurisdiction in patent infringement cases. Proceedings are started by summoning the opposing party with a writ. There are three forms of infringement proceedings:

- Provisional measures in preliminary proceedings. An injunction may be obtained within months, or in urgent cases within days. The provisional judgment must be followed by accelerated proceedings on the merits. A preliminary injunction can be claimed between the parties or ex parte.
- Accelerated proceeding on the merits. First the claimant must petition the court for permission. The court then sets a strict schedule, including pre-set dates for serving the writ, the statement of defence and pleadings. The proceedings last between 11 and 15 months.
- Proceedings on the merits. These generally last from one year up to two and a half years, excluding appeal proceedings.

The following final remedies are available to a patent owner:

- Damages.
- Lost profits.
- The infringer’s profits resulting from the infringement.
- Compensation for legal costs incurred.
- Surrender or destruction of infringing products.
- Information about the infringing trade.
- A correction (for example, in a public newspaper).


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

The EU "8+2+1" rule applies:

- Generics cannot be authorised until after eight years from authorisation of the reference medicinal product (data exclusivity period). A generic marketing authorisation is based on the clinical and preclinical data submitted for the reference medicinal product.
- Generics cannot be marketed before a marketing exclusivity period of ten years has expired from authorisation of the reference medicinal product. This is extendable by one extra year, due to the addition of a significant new indication.

For medicinal products which have been designated as an orphan medicinal product, the originator company is granted ten years of market exclusivity per therapeutic indication granted for a designated condition, under Regulation (EC) 141/2000 on orphan medicinal products.

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

Dutch trade marks are part of Benelux trade marks and are subject to the Benelux Convention on Intellectual Property, which entered into force on 1 October 2013.
In principle, any sign which can be geographically represented, and serves to distinguish the goods or services of an undertaking, can qualify for a Benelux trade mark.

**Scope of protection**
A medicinal brand can be registered as a trade mark, if it meets the legal requirements. However, a sign cannot qualify for a Benelux trade mark if it is any of the following:
- Consists solely of a shape which results from the nature of a good.
- Gives a substantial value to the good.
- Is necessary to obtain a technical result.

8. **How is a trade mark registered?**

**Application and guidance**
An application for a Benelux trade mark must be made to the Benelux Office for Intellectual Property, located in The Hague, either by an online or paper application. Its website [www.boip.in][1] provides detailed guidance on the application procedure and fees.

**Process and timing**
On receiving a complete application for a Benelux trade mark, the Benelux Office for Intellectual Property will either:
- Fix the filing date.
- Inform the applicant about the reasons for not fixing a filing date, and grant a one-month additional period for the applicant to complete the application. This period can be extended to up to six months.

On meeting the conditions for fixing the filing date, the Benelux Office for Intellectual Property will publish the application.

A third party can start written opposition proceedings with the Benelux Office for Intellectual Property within two months, starting from the date on which the relevant trade mark application has been published.

If the Benelux Office for Intellectual Property rejects the application, the applicant can raise objections before the Benelux Office for Intellectual Property within one month from the date of the refusal. This period may be extended on the applicant’s request. If the objections are not resolved within this period, the Benelux Office for Intellectual Property will notify the applicant of the whole or partial refusal. Within two months from the date of this notification, the applicant can appeal against the refusal before The Hague Appeal Court.

Trade mark registration occurs on the date that the Benelux Office for Intellectual Property establishes that the application meets all the requirements of the Benelux Convention on Intellectual Property and its implementing regulations.

9. **How long does trade mark protection typically last?**

A trade mark registered with the Benelux Office for Intellectual Property has a protection period of ten years, starting from the date of filing. On payment of the renewal fee, during the six months before expiry of the registration, the trade mark can be renewed for further periods of ten years each.

10. **How can a trade mark be revoked?**

A Benelux trade mark can be revoked if, among other things:
- Within a continuous period of five years, for no proper reason it has not been put to use in Benelux territory in relation to the goods/services that it has been registered for.
- The trade mark becomes a generic name for the product/service it has been registered for, due to acts or inactivity of the owner.
- Due to its owner’s acts, the trade mark becomes liable to mislead the public, particularly as to the nature, quality or geographical origin of the registered goods/services.

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

**Conditions**
A Benelux trade mark is infringed if, among other things, a third party:
- Uses in the course of his trade a sign which is identical to the registered trade mark for identical goods/services corresponding to the trade mark.
- Uses a sign similar to the trade mark, which causes a likelihood of confusion among the public, which also leads to the likelihood of association with the trade mark.
- Uses a sign identical to a Benelux trade mark with a reputation, and takes unfair advantage of it or the use is detrimental to the distinctive character or the repute of the trade mark.

**Claim and remedies**
The owner of a trade mark can start infringement proceedings by serving a writ of summons and initiating proceedings at the Dutch court in the district where the infringement takes place. However, if the trade mark is a Community trade mark, the courts of The Hague have exclusive jurisdiction. The claimant can claim the following remedies, among other things:
- Injunction.
- Damages.
- Profits resulting from the infringement.
- Correction (in a public newspaper or on the internet).
- Information about the distribution chain.
- The infringing products and manufacturing material used to produce the products, or ask the court to destroy such products.
- Compensation for legal costs.

Provisional measures can be applied for among the parties or ex parte.

The trade mark owner can, in certain circumstances, seize infringing products and seize evidence of the infringement to preserve evidence.

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

Regulation (EC) 1383/2003 on action against counterfeit and pirated goods (Counterfeit Goods Regulation) is enforceable by the Dutch Customs Authority. This Customs Authority can take action against a shipment if they think it contains counterfeit goods, on

[1]: global.practicallaw.com/lifesciences-guide
their own initiative if they suspect this or on a right holder’s request if he thinks his rights are about to be infringed.

If the counterfeit goods are out of the control of the Dutch Customs, the right holder can request assistance from the Tax and Customs Administration’s investigation department, the FIOD (Fiscale Inlichtingen- en Opsporingsdienst).

The Netherlands has also implemented the Intellectual Property Directive and takes enforcement action based on the relevant EU legislation.

Under the recently implemented Directive 2011/62/ amending Directive 83/EC as regards the promotion of the entry into the legal supply chain of falsified medicinal products, active pharmaceutical ingredients for medicinal products from outside the EEA must either:

- Originate from a non-EEA country named on the white list in Directive 2011/62.
- Be supported by a written good manufacturing procedure certificate.

These requirements also apply to the export of medicinal products. Forms to apply for a registration certificate and documents to attach are available on the Farmatec website (www.farmatec.nl).

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 Netherlands: 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 Authority for Consumers and Markets (www.acm.nl/en) enforces the Dutch Competition Act 1997 (as amended).

In 2013, the Authority for Consumers and Markets was not involved in any investigation concerning the anti-competitive conduct of a pharmaceutical undertaking.

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

The typical issues that arise in the Dutch market are the same as those at EU level, such as:

- Anti-competitive cross-licences.
- Settlement agreements involving a generic competitor delay element.

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

In addition to any cases pending and decided at EU level, we have not seen any competition law complaints or competition law claims in litigation concerning generic entry in The Netherlands in 2013.

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

Abuse of dominance issues arose in the pharmaceutical sector in relation to a refusal to supply pharmacies. A pharmaceutical company used a quota system to supply pharmacies and terminated the distribution agreement with a pharmacy for default. The pharmacy argued that this was an abuse of a dominant position. This claim was not upheld by the court (District Court of Utrecht, 14 November 2006, LJN AZ2861).

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

There have been several court cases regarding parallel imports and parallel distribution over the years, mainly concerning IP and in one case concerning the European Medicines Agency (EMA)’s task to control the marketing of medicinal products.

For instance, the Court of Rotterdam has stated that the requirement to repack medicinal products only relates to the need to market the product in the state it is imported into. The method of repackaging/relabelling and style of new labels or packaging should only be reviewed to ensure that the trade mark owner’s reputation is not damaged (Rotterdam district court, 17 December 2009, 342087/KG ZA 09-1152).

In a case regarding a marketing authorisation (rather than intellectual property rights), the district court of The Hague found that the Regulation (EC) 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMA Regulation) has no explicit rule that an importing party should verify with EMA whether the requirements imposed on parallel imports are met before the products can be marketed. The EMA Regulation intends the EMA to carry out its controlling tasks after products have been marketed (District Court of The Hague 19 March 2008, 304170/KG ZA 08-174).

The Court of Appeal has rejected a defence based on exhaustion, and found that GlaxoSmithKline’s trade mark rights had been infringed by a party importing medicinal products from Africa (Court of Appeal, The Hague, 23 February 2000).

Reference may also be made to judgments of the Court of Justice of the European Union, for example Case C-457/10 of 06-12-2012 (AstraZeneca). This has a significant impact on the situation in, among other jurisdictions, The Netherlands.

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?

A Dutch natural person and legal entity can license foreign patents and trade marks without the prior approval of a Dutch state authority. The Authority for Consumers and Markets can exercise subsequent supervision if the royalties are set at a level or under conditions that violate competition law.

Licences, which have been entered in the applicable registries, can be invoked against third parties who, for example, have bought a patent or trade mark under which a licence was granted.

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 Netherlands: overview.
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**Areas of practice.** Life sciences

**Recent transactions**
- Acting for a pharmaceutical company in litigation against a competent authority for marketing authorisation.
- Advising and representing a pharmaceutical company in respect of pricing and reimbursement.
- Advising and representing several companies in respect of tax legislation.
- Implementing compliance SOPs for a pharmaceutical company.
- Advising governments and international organisation on pharmaceutical law and policy (Moldova, Ukraine, and East African Community).

**Languages.** Dutch, English

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**Publications.** Editor of *Jurisprudentie Geneesmiddelenrecht*, Member of the Editorial Board of MedNous, *DIA Global Forum and Scrip Regulatory Affairs*. Author of many publications on pharmaceutical law.

**Professional qualifications.** Groningen University, 1991 to 1996; Stockholm University 1996 to 1997; stagiair at DG Competition, European Commission, 1997 to 1998; visiting teacher Regulation of Life Sciences Products at Twente University, 2012 to present

**Areas of practice.** Life sciences; competition law; IP

**Recent transactions**
- Acting for a pharmaceutical company in patent litigation and IP licensing matters.
- Advising several pharmaceutical companies regarding personal health data regulation.

**Languages.** Dutch, English, German, French, Swedish

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Areas of practice. IP licensing; research and development driven contracts; pharmaceutical contracts; corporate law; advising on the various phases of the product life cycle, including spinning out businesses from universities, obtaining financing, securing strategic partners, IP exploitation, clinical development, market approval, and commercialisation.

Professional associations/memberships. Frequently acts as a jury member for life sciences venture awards and grant committees; lectures at Leiden University and various Master classes in the sector; in-depth knowledge of the biotech and technology markets.