

## The Netherlands

### Legal basis

Patents Act of 15 December 1994 (Dutch Patent Act, hereinafter DPA), which also implements Art. 12 Biotech Directive (Art. 57(5) DPA).

The text in the DPA is not always entirely consistent with that of Art. 31 TRIPS. In case of a conflict, the text of the TRIPS Agreement will most likely prevail<sup>1</sup>.

### Grounds for applying for a licence

Under the Dutch Patent Act (DPA), there are five grounds on which a licence may be obtained against the wishes of the patentee. See Art. 57(1), 57(2), 57(4) and (5), 59, and 60 DPA<sup>2,3</sup>:

- public interest;
- lack of sufficient application by the patentee (*non usus*);
- ownership of dependent patents (or dependent plant breeder's right in respect of the plant variety);
- national defence; and
- the Euratom treaty.

The focus below will be on the first three grounds.

### General procedure

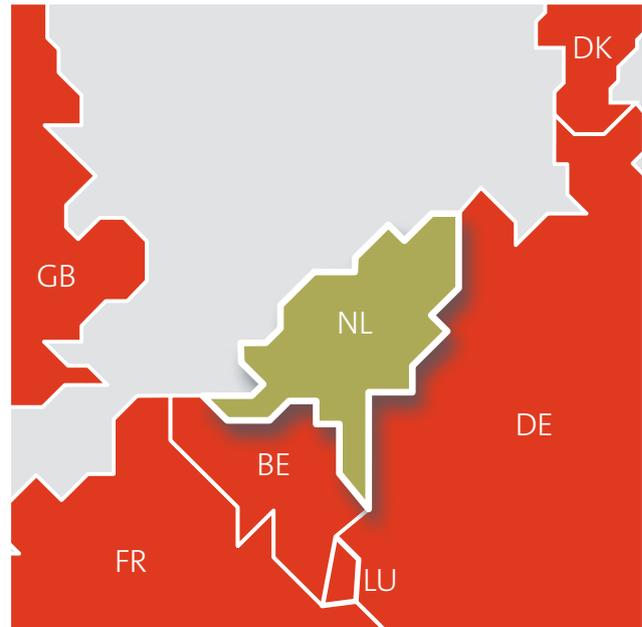
Under Article 57(1) DPA, a compulsory licence in the public interest may be granted by the Minister of Economic Affairs ("the Minister").

A compulsory licence based on *non usus* or on dependent patents may be granted by the District Court of The Hague.

The procedures for obtaining compulsory licences are laid down in Arts. 57 to 60 DPA.

### Procedure to obtain a licence in the public interest

The procedure for obtaining a licence in the public interest is set out in Art. 57(1) DPA.



A request for a compulsory licence in the public interest must be filed in writing with the Minister.<sup>4</sup> As the DPA does not provide for a time frame in which the decision must be made, the decision has to be made "within a reasonable period after receiving the application" which is at most eight weeks after receiving the application.<sup>5</sup> This period can be extended by "a reasonable period", which is usually also eight weeks. Art. 57(1) DPA stipulates that before deciding upon the request the Minister shall ascertain, unless urgency dictates otherwise, whether the patentee is willing to grant a licence voluntarily and on reasonable terms. To this end, the Minister shall give the patentee the opportunity to express his views on the request for a compulsory licence. This does not seem fully in line with Art. 31(b) TRIPS, which says that parties must first negotiate in good faith. As the TRIPS Agreement prevails, the applicant should probably first try to obtain a voluntary licence from the patentee also with compulsory licences based on the public interest.

Art. 83(3) DPA gives the District Court of The Hague, a specialised patent court, the discretion to stay pending proceedings, e.g. an infringement procedure, if there are other proceedings pending which may influence the outcome of the procedure at hand. Arguably, a request for a compulsory licence qualifies as such. The courts have broad discretionary powers in this respect. They tend to assess the

<sup>1</sup> International treaties have direct force in the Netherlands if it concerns a stipulation which is sufficiently specific to have a general effect, also referred to as a self-executing provision. In case of a conflict between such a self-executing provision in an international treaty and the national law, the treaty prevails (see also decision Roche/Primus where the Supreme Court ruled that Article 45(1) of the TRIPS Agreement is one such self-executing provision).

<sup>2</sup> An informal – and not fully up-to-date – English translation of the entire DPA can be found at: [https://english.rvo.nl/sites/default/files/2013/12/ROW95\\_ENG\\_niet\\_officiele\\_vertaling\\_0.pdf](https://english.rvo.nl/sites/default/files/2013/12/ROW95_ENG_niet_officiele_vertaling_0.pdf)

<sup>3</sup> In accordance with Article 57(a) DPA and Article 31(c) TRIPS, a compulsory patent licence in the field of semiconductor technology may be granted only for non-commercial use by the government or in order to combat an act that has been determined to be restrictive of competition after judicial or administrative proceedings.

<sup>4</sup> Article 4:1 of the *Algemene Wet Bestuursrecht* (General Code of Administrative law; GCA)

<sup>5</sup> Article 4:13 GCA

probable outcome of the other proceedings and put that in an equation with the respective interests of plaintiff and defendant.

### Procedure to obtain a licence for *non usus* or applying a dependent patent

A compulsory licence based on *non usus* or on dependency can be granted by the District Court of The Hague (Art. 80(c) and (d) DPA) if the patentee refuses to grant a licence (Art. 58 DPA)<sup>6</sup>. It has to be requested by writ. Although not mentioned in the provision, it is probably also possible to file the request by way of counterclaim in infringement proceedings initiated by the patentee at the District Court of The Hague.

### Effective after registration in the Dutch Patent Register

Art. 58(5) DPA provides that a decision of the Minister on a request for a compulsory licence in the public interest, or a (final, no longer appealable) District Court decision on a request for a compulsory licence for *non usus* or dependency, shall be registered in the Dutch patent register by the Dutch Patent Office. The licence shall enter into effect only once it is registered (with the exception of a licence for dependency, which may have retroactive effect as of the moment of registration in the Dutch patent register of the writ of summons claiming the licence).

### Compulsory licence as preliminary relief?

Compulsory licences cannot be granted by the Preliminary Injunction (PI) Judge. It may be possible though that a PI Judge dismisses or suspends a PI in view of pending or announced compulsory licence proceedings depending on the likelihood of success, also in view of the balance of interests at stake (although the licence itself is only effective after the granting decision has become final and is registered – see above).

## Rules common to all types of compulsory licences

### Previous negotiations failed

Art. 31(b) TRIPS stipulates that a compulsory licence may only be granted if

*“[...] the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.”*

TRIPS makes previous failed negotiations between the applicant and the patentee a prerequisite for a compulsory licence. A compulsory licence is a last resort. Only if, after a reasonable period of time, negotiations are still unsuccessful, there may be room for a compulsory licence.

The DPA does not contain the same requirement, but the TRIPS provisions should prevail in case of a conflict with the DPA. Therefore also in the Netherlands, a party applying for a compulsory licence under the DPA must be able to show that previous attempts to conclude a licence agreement all failed. He must show that he negotiated in good faith, e.g. he must be able to show that the licence fee he offered is reasonable.

### Licence fees (Art. 58(6) DPA)

If a compulsory licence is granted, the licensee must pay a licence fee to the patentee. The DPA assumes that the patentee and the licensee may negotiate and agree on a licence fee after a compulsory licence has been granted. However, if no agreement can be reached, either party may request the District Court of The Hague to determine the fee. The Supreme Court determined in 1942 that the District Court has a large degree of freedom in determining the fee.<sup>7</sup> Before granting a compulsory licence the court may impose the condition that the licensee puts up a security for licence fees due (Art. 57(1) and 58(4) DPA).

### Particularities of the compulsory licence

According to Art. 58a(1) DPA, a compulsory licence based on the general interest, *non usus* or dependent patents is non-exclusive. Such a licence cannot be transferred unless the relevant part of the undertaking is also transferred (Art. 58a(2) DPA). Pursuant to Art. 58a(3), such a compulsory licence may be revoked when the circumstances that led to the grant are no longer present and it is unlikely that the situation will revert.

<sup>6</sup> Before 1995, the now-defunct Dutch Patent Council (DPC) had jurisdiction. DPC case law can still be relevant, as the material provision has not changed. In these proceedings, the “regular” rules of civil procedure apply.

<sup>7</sup> Supreme Court 17 December 1942, NJ 1943, 39. See also District Court The Hague 8 July 1987, BIE 1988, 28 (Bronchitis vaccines for poultry II) and District Court The Hague 20 March 2002, BIE 2002, 82 (Shrimp sorting sieve III).

### A national right: no EU-exhaustion

If a compulsory licence is obtained, this licence will apply to the territory of the Netherlands. Products put on the market under a compulsory licence are not considered to be brought on the market with consent of the patentee<sup>8</sup>. Therefore the EU-doctrine of European Union-wide exhaustion, i.e. that products that are put on the market in one EU member state by or with the consent of the patentee can be freely moved to other EU member states, does not apply.

### Requirements for a compulsory licence in the public interest

Under Art. 57(1) DPA, a compulsory licence may be granted by the Minister of Economic Affairs (“the Minister”)<sup>9</sup> “if the public interest so dictates”. The terms of a compulsory licence in the public interest are determined by the Minister (Art. 57(1) DPA).

The concept of public interest must be interpreted broadly and is not limited to Economic Affairs only. In the decision in a case between La Buvette and Utina (in which the compulsory licence was denied), the Minister wrote:

*“The law does not describe more precisely what public interest is; in general this includes the government’s policy objectives. Since the temporary monopoly a patent grants is itself within the scope of these policy objectives, one policy objective will have to be weighed against the other in order to determine whether or not there are sufficient grounds for the application of this exception. The term “dictates” signifies that priority should not be given lightly to policy objectives other than those on which the patent system is based.”<sup>10</sup>*

This indicates that there must be a pressing policy or general public interest served before a compulsory licence based on the public interest can be granted. According to a decision from 1932, the interests of an individual company to better compete in the market was not enough.<sup>11</sup> Mere benefits for the applicant are therefore insufficient.

According to a later decision from 1972, a compulsory licence can only be granted in cases where the behaviour of the

patentee borders to misuse of his patent rights and its refusal to grant a licence have created a situation that is clearly contrary to public interest. The mere fact that the applicant could provide the products (in this case patented drugs) for a lower price was not sufficient to establish that the public interest dictates a compulsory licence. The applicant would have to show that the patentee charged exorbitantly high prices to the effect that it was abusing its patent rights.<sup>12</sup> Higher prices as such are also insufficient since the patentee will have to earn back R&D costs<sup>13</sup>.

Therefore for this provision to apply there must be a clear and pressing public interest which is not only served by the compulsory licence, but is actually demanded. Lower prices in general are insufficient.

### Requirements for a compulsory licence for *non usus*

A compulsory licence may be granted in case of lack of sufficient application of the patent (*non usus*) (Art. 57(2) DPA).

If three years have elapsed since the grant of the patent,<sup>14</sup> and neither the patentee nor any licensee operates an undertaking in which the patented invention is being manufactured or applied, in good faith and on sufficient scale, the patentee has an obligation to grant the licence needed for such manufacture or application unless he can show a valid reasons for the lack of application.

The provision states that the application must take place within the Kingdom of The Netherlands, but also mentions the possibility of designating other states via a statutory instrument.<sup>15</sup> Art. 28 of the Implementing Regulation to the DPA<sup>16</sup> designates the European Union and the other members of the European Economic Area, and all WTO member states provided that the production in those states ensures a sufficient supply in the Kingdom of The Netherlands. Therefore *non usus* may only be assumed if (1) the invention is not applied in the European Economic Area and (2) companies in other WTO member states are not able to provide sufficient quantities.

<sup>8</sup> Judgment of 9 July 1985, Hoechst v Pharmon C-19/84, ECLI:EU:C:1985:304. See also: [http://www.ippt.eu/files/1985/IPPT19850709\\_ECJ\\_Pharmon.pdf](http://www.ippt.eu/files/1985/IPPT19850709_ECJ_Pharmon.pdf)

<sup>9</sup> Until 1977, this power resided with the now-defunct Dutch Patent Council (DPC). However, the material provisions have not changed since 1910.

<sup>10</sup> Decision Minister 9 January 1980, BIE 1981, p. 185 e.v.

<sup>11</sup> Appeals Division Dutch Patent Council 17 February 1932, BIE 1932, p. 136

<sup>12</sup> Appeals Division Dutch Patent Council 19 July 1972, BIE 1972, nr. 72, p. 236

<sup>13</sup> The government referred to this decision when it shifted the power to grant compulsory licences from the DPC to the Minister and was asked to elaborate on the meaning of “public interest”. See MvA, Kamerstukken II 1975/76, 13 209, nr. 8, p. 8-9. (R 967). The government also mentioned that in these cases the licensing fees that would have to be paid to the patentee pursuant to the compulsory licence would have to be taken into account when calculating the price difference.

<sup>14</sup> For patents granted under the European Patent Convention, the time frame is three years since the date on which the grant has been published pursuant to Article 97(4) EPC.

<sup>15</sup> In Dutch: *Algemene Maatregel van Bestuur* or AMvB

<sup>16</sup> Uitvoeringsbesluit Rijksoctrooiwet 1995

The request for a compulsory licence based on *non usus* will be denied if the patentee can show a valid reason for the *non usus*. Valid reasons may be being unable to apply the patent<sup>17</sup>, the circumstance that supply in the Netherlands was guaranteed by production in another country (outside the EEA)<sup>18</sup>, or circumstances beyond the patentee's control such as the lack of necessary permits or *force majeure*.

### Requirements for a compulsory licence for dependent patents (and dependent plant breeder's rights)

Art. 57(4) DPA states that a compulsory licence may also be obtained if the patented invention is necessary for the application of a later patented invention (a dependent patent). A similar provision for dependent plant breeder's rights is laid down in Art. 57(5) DPA.

A dependent patent will often entail an improvement or a new application of the earlier patent, but that is insufficient to constitute "an important technical advance of considerable economic significance". The requirement of a considerable advancement is perceived as a particularly high threshold.<sup>19</sup>

Under old Dutch case law the element that applying an earlier patent was "required" for applying a later patent was construed broadly; a compulsory licence was considered "required" if without that licence the younger patent could not be exploited in a technically and economically sensible manner.<sup>20</sup> It is not certain whether this is still good law under the current wording of Art. 57(4) DPA and the TRIPS Agreement.

In deciding on a request for a compulsory licence for *non usus* or dependency, the Court has full discretion to dictate the terms of the licence (Article 58(4) DPA).

## Appeal/review

After a decision by the Minister about a compulsory licence in the public interest, both parties (applicant and patentee) may lodge an objection,<sup>21</sup> which is a complaint sent to the Minister himself to re-evaluate his previous decision. The term to submit an objection is six weeks.<sup>22</sup> After the decision on objection, an appeal can be lodged to the administrative chamber of the District Court of The Hague.<sup>23</sup> A final appeal may be lodged to the Council of State (*Raad van State*). Both the objection and the appeal have suspensive effect, unless the decision of the Minister provides otherwise on grounds of urgency.<sup>24</sup>

Appeals against decisions about compulsory licences for *non usus* or applying a dependent patent by the District Court of The Hague may be appealed before the Hague Court of Appeal. Subsequent appeal is possible before the Dutch Supreme Court (the latter on points of law only).

## Statistics and jurisprudence

Although the DPA contains detailed rules on compulsory licences, their practical relevance has been limited. The most recent cases date back to the mid-1990s and in most cases the request was denied. There is also limited literature available. This means that (1) *a priori* requesting a compulsory licence is challenging although (2) the doctrine of compulsory licences is not well established and there are only limited guidelines to assess the chances of succeeding with such a request. Much will probably depend on the facts and circumstances of the case.

Some of the most recent relevant cases (in addition to the cases already described above):

17 Special Divison Dutch Patent Council 5 September 1995, BIE 1996, nr. 43, p. 156: "the Special Division, along with Medrad, is of the opinion that the criterion for the presence of a valid reason for non-application should not be so strict that one could speak of being unable to exploit".

18 Special Divison Dutch Patent Council 5 September 1995, BIE 1996, nr. 43, p. 155. This part of the decision has now been incorporated in the Implementing Regulation to the DPA which designates all WTO member states as long as supply in the Netherlands is guaranteed.

19 Huydecoper en Van Nispen, Industriële eigendom; deel 1, Bescherming van technische innovatie, Kluwer: Deventer 2002, III.7.5.14 (p. 317)

20 Huydecoper en Van Nispen, Industriële eigendom; deel 1, Bescherming van technische innovatie, Kluwer: Deventer 2002, III.7.5.16 (p. 318)

21 Since these are both "interested parties" as meant in Article 1:2 GCA; there may also be other interested parties.

22 Article 6:7 GCA

23 Article 8:7 GCA

24 Article 57(1) DPA

**President of the District Court The Hague (preliminary proceedings), ev3 c.s. / The Regents, 11 December 2003, KG 03/1257 – compulsory licence argument denied:**

In these proceedings ev3 c.s. requested a stay of the execution of an injunction obtained by The Regents in merits proceedings, *inter alia* arguing that ev3 c.s. would be granted dependent patents in the future which would lead to ev3 c.s. having a right to a compulsory licence. The court ruled that in preliminary (execution) proceedings such as these, there is no room to assess these claims – which were disputed by The Regents.

**President of the District Court The Hague (preliminary proceedings), Cordis / Medinol, 26 August 2003, KG 03/835 – compulsory licence argument denied:**

In these proceedings, Cordis requested that the court would prohibit Medinol from executing the (provisional) injunctive relief it had obtained in different patent proceedings before the Court of Appeal The Hague. As one of the grounds for this request Cordis asserted it would obtain a compulsory licence for *non usus*. Medinol disputed this by asserting that it had timely made use of the patent in Ireland and that moreover it produced the patented stents on such scale in Israel that it could supply Europe and the Netherlands. In light of these counterarguments the court considered that it could not be deemed likely that Cordis would obtain a compulsory licence, and that in preliminary proceedings this point could not be further investigated.

**President of the District Court The Hague (preliminary proceedings), Cook / Fujinon, 17 March 1995, KG 95/268 – compulsory licence argument denied:**

Cook claimed a preliminary injunction against the stents of Fujinon. One of Fujinon's defences was that the Minister of Economic affairs would (in the future) grant a compulsory licence. The court considered this to be irrelevant for the question whether an injunction should be granted: i) the compulsory licence would not have retroactive effect, i.e. for past infringement a ruling would still be needed, and ii) if a compulsory licence were to be granted from that moment on there would be no infringement anymore and therefore Fujinon would not suffer from the injunction anymore either.

**President of the District Court The Hague (preliminary proceedings), Chicago Metallic Continental / Maars c.s., 1 May 1991, KG 91/312 – compulsory licence argument denied:**

Chicago claimed a preliminary injunction against Maars c.s. One of the defences was that Maars c.s. had a dependent patent, regarding which it would submit a request for a compulsory licence to the Dutch Patent Council. The court ruled that the possibility of submitting a request for a compulsory licence is not enough to avoid an injunction. In addition it considered that *prima facie* it appeared that Maars c.s.' patent was not dependent on the patent of Chicago, leading to the conclusion that it would be unlikely that a compulsory licence would be granted.

