

Sweden

Legal basis in Sweden

Sections 45-50 of the Swedish Patents Act No. 837 of 1967 as amended (hereinafter PA).

Art. 12 Biotech Directive is implemented through Section 46a PA.

As EU Regulation 816/2006 has direct effect in Sweden, it has not been explicitly implemented in Swedish legislation. Certain articles, such as Arts. 12 and 16(2) regarding the provision of information and Arts. 14 and 16(3) regarding the competent authority have led to some amendments of other Swedish legislative Acts, implementing those obligations.

Grounds for applying for a licence

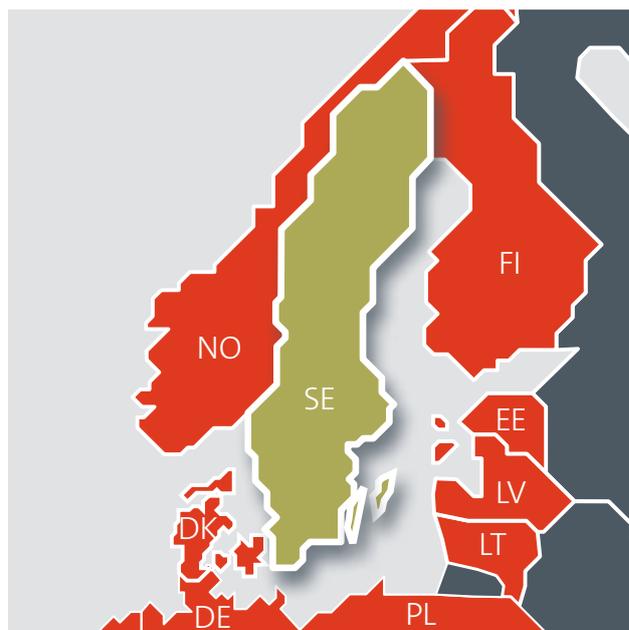
Sections 45- to 50 PA provide a legal right to obtain a court-ordered compulsory licence to a patent in different scenarios.

The first scenario (Section 45 PA) concerns lack of exploitation of a patented invention in Sweden. The legal criteria for the grant of a compulsory licence in this scenario are that:

- (at least) three years have passed from the grant of the patent and four years from the date of filing of the patent application;
- the invention is not exploited to a reasonable degree in Sweden; and
- there is no acceptable reason as to why the invention is not being exploited.

As to item (ii), it is sufficient that products relevant to the invention are imported from member states in the EU or a state/region that has acceded to the agreement on the creation of the WTO.

A second scenario (Sections 46 and 46a PA) concerns the situation where a granted patent or plant variety right (A) is dependent on another patent (B) in the sense that the commercial exploitation of the patent/plant variety right A involves infringement of patent B. The holder of patent/plant variety right A can then obtain a licence to patent B provided that he/she shows that patent/plant variety right A constitutes an important technical advance of substantial economic interest in comparison to the invention covered by patent B. In this case, a licence is granted and the holder of



patent B is entitled to a corresponding licence to patent/plant variety right A.

The third scenario (Section 47 PA) concerns the situation where there is public interest of utmost importance requiring a compulsory licence to be granted to someone who intends to exploit the invention commercially.

A fourth scenario (Section 48 PA) concerns the situation where someone, after the filing but prior to the publication of a patent application, has started to exploit the invention on a commercial scale or has made substantial preparations for such exploitation. The right to a compulsory licence is conditional on the party seeking a licence not having been aware of the patent application and was not in a position to obtain information in this respect either. The right to a licence is triggered by the grant of the patent, but the licence can also cover the application stage.

The general rules on compulsory licences (Section 49 PA) further provide that:

- (i) a licence may be granted only to someone who has the capacity to exploit the invention in an acceptable manner;
- (ii) the party seeking a licence must prove that he/she without success has approached the patentee to obtain a voluntary licence on reasonable terms,
- (iii) a compulsory licence does not prevent the patentee from using or granting other licences to the patent, and that

- (iv) a compulsory licence can only be transferred together with the business in which it is used or intended to be used, and in respect of licences to holders of dependent patents/plant variety rights, the patent or plant variety right in question.

Compulsory licences can also be granted based on EU Regulation 816/2006, which has direct effect in Sweden. The Swedish Medical Product Agency is the competent authority in respect of Art. 14 of the Regulation.

General procedure

The Patent and Market Court is competent to grant a compulsory licence.

A request for a compulsory licence is filed as a civil law suit under the general rules of the Swedish Procedural Code, as complemented by the specific procedural provisions in the PA (mainly relating to the exclusive venue and composition of the court). The case is initiated when the party seeking a licence files an application for summons. The parties have the burden of advancing their case, e.g. by providing evidence, and the court may reach a decision solely within the framework of what the parties have claimed and admitted. There are no explicit provisions allowing for the grant of a compulsory licence as preliminary relief and, to the best of our knowledge, this has not been done in practice. It is conceivable that the court would consider arguments concerning the right to a compulsory licence in deciding whether to grant preliminary injunctive relief against a defendant. In one case, the defendant argued that the patentee's failure to produce sufficient amounts of medicinal products to ensure proper treatment for patients suffering from certain diseases constituted extraordinary grounds for not issuing a preliminary injunction (Stockholm District Court, Case No T 5784-10). However, the case was settled and the issue was never tried before the court.

The court has discretion as to the terms of the compulsory licence (Section 50 PA). Within the framework created by the parties' positions, the court has the authority and discretion to decide to what extent the invention may be used, the compensation to be paid and other terms of the licence agreement. The general limitations set out in Sections 45 and 49 PA limit the court's discretion. For example, compulsory licences based on lack of exploitation in Sweden cannot cover import, and compulsory licences based on previous use can cover only the use that the licensee has in fact undertaken. The scope of the licence granted shall not be wider than what is justified by the facts of the case. A

compulsory licence may not prevent the patentee from using the invention or from granting further licences; see comment on Section 49 PA above.

There are legal commentaries addressing the relevant provisions of the Patents Act, the most recent one being "*Patentlagen – en kommentar och en jämförelse med EPC och PCT*" (The Patents Act – a commentary and comparison with the EPC and PCT) by B. G. Nilson and C. Holtz from 2012, but these are rather limited and focused on the legal criteria as such and the legislative history of the different sections.

Appeal/review

An appeal to the Patent and Market Court of Appeal is subject to the grant of leave to appeal. A further appeal to the Supreme Court is then subject to a double requirement for leave to appeal (i.e. first from the Patent and Market Court of Appeal and subsequently from the Supreme Court).

Statistics and jurisprudence

We are not aware of any precedent cases concerning the grant of a compulsory licence under the current rules. There are a few such cases under the old Patents Act (prior to 1967), which are of little or no relevance but nevertheless briefly accounted for below.

NJA 1937 p. 90: regarding the possibility to avoid a compulsory licence by starting to exploit or expanding the exploitation of the patent in Sweden after the filing of an action for a compulsory licence (where the answer was negative). The case concerned patents with military application and a licence was granted.

NJA 1945 p. 110: regarding the existence of a valid reason for not exploiting the invention in Sweden where importing from Germany was not considered sufficient and a licence was granted.

NJA 1947 p. 692 II: regarding a case in which the patent was exploited (in Sweden or abroad). The patented products were manufactured in Sweden and the fact that raw material was imported was not considered relevant. No licence was granted.