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Destruction of patent protected products manufactured outside Sweden

– Is Section 59 of the Swedish Patents Act on corrective measures contrary to EU law?

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1. INTRODUCTION

The possibility for a patent holder that has suffered an infringement to apply for corrective measures such as, e.g. recall or destruction of the infringing goods serves the purpose of enforcing a court-ordered prohibition in practice and is an important tool in upholding the exclusive right. According to Section 59 of the Swedish Patents Act[1], *"upon a claim by a party that has suffered a patent infringement, the Court may, insofar as is reasonable, decide that a patent-protected product that has been manufactured without the consent of the patent holder shall be recalled from the channels of commerce, changed, taken into custody for the remainder of the patent term or be destroyed or that some other measure shall be taken in respect of it. The same applies to implements that have been, or have been intended to be, used in connection with the infringement."*[2]

The possibility for the courts to decide upon corrective measures such as, e.g. destruction, following a finding of patent infringement, has existed for a long time in Swedish patent law. Similar measures are found in the other Swedish intellectual property statutes. Since the implementation of the harmonisation measures pursuant to the Directive (2004/48/EC)[3] on the enforcement of intellectual property rights (the "Enforcement Directive"), the provisions governing corrective measures in Section 59 of the Swedish Patents Act must be interpreted in conformity with Article 10 of the Directive.

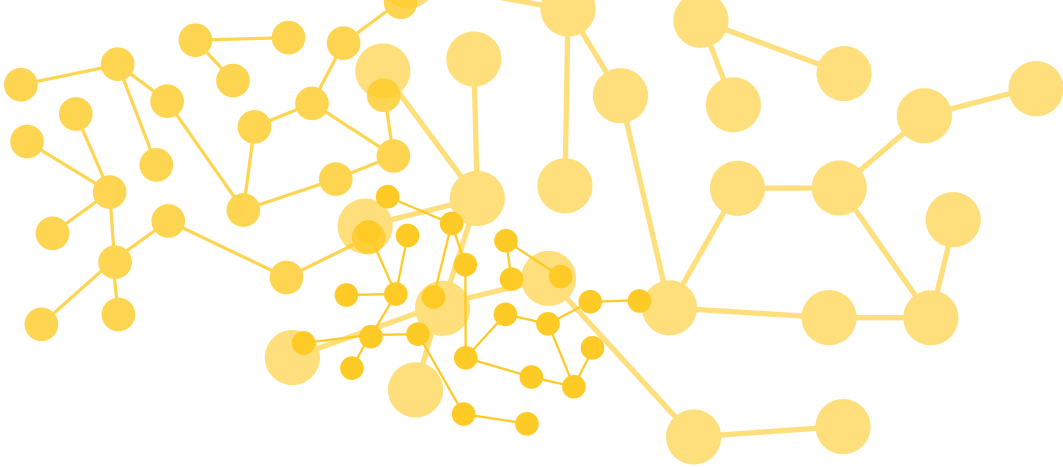
According to Article 10 of the Enforcement Directive, Member States shall ensure that the competent judicial authorities may order, at the request of the applicant, that appropriate measures be taken with regard to goods that they have found to be infringing an intellectual property right and, in appropriate cases, with regard to materials and implements principally used in the creation or manufacture of those goods. Such measures include, e.g. destruction. In considering a request for corrective measures, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account.
The principle of interpretation of national law in conformity with the provisions of an enacted directive is firmly anchored in EU law. But where the wording of a national provision is not in line with the corresponding directive provision, such directive-loyal interpretation may risk leading to legal uncertainty. Such issues arose in a case before the Swedish Patent and Market Court of Appeal (the "PMCA") in December 2020,[4] regarding the scope of Section 59 in the context of destruction of goods. In this case, an issue arose regarding the interpretation of Section 59 the Swedish Patents Act in conformity with Article 10 of the Enforcement Directive thereby trigging a question pertaining to the extent of such interpretation when the wording of the national provision is not in conformity with the wording of the Directive's provision.

2 THE PATENT AND MARKET COURT

2.1 The Reasons

The case concerned a patent infringement claimed by the plaintiff AstraZeneca AB versus the defendant Sandoz A/S. AstraZeneca alleged that Sandoz' marketing of the pharmaceutical *Fulvestrant Sandoz* amounted to an infringement of AstraZeneca's patent to the use of the pharmaceutical fulvestrant in the preparation of a pharmaceutical formulation for the treatment of a benign or malignant disease in the breast or reproductive tract by intra-muscular administration.[5] Sandoz had counterclaimed that the patent was invalid. In the event that the Patent and Market Court (the "PMC") would find that the patent was valid, Sandoz had admitted that the use of the pharmaceutical *Fulvestrant Sandoz* amounted to infringement of AstraZeneca's patent. However, Sandoz contested some of AstraZeneca's claims for relief, among them the claim based on Section 59 of the Patents Act for destruction of the *Fulvestrant Sandoz* products that Sandoz had or might have in their possession in Sweden.

The PMC found that the patent was valid and since Sandoz had admitted infringement in such situation, the Court, *inter alia*, proceeded to the interpretation of Section 59 of the Patents Act. Sandoz held that since the products in question were not manufactured in Sweden, Section 59 of the Patents Act was not applicable, and that it would neither be reasonable nor proportionate to order Sandoz to destroy the *Fulvestrant Sandoz* products. Sandoz argued that destruction as well as other corrective measures according to Section 59 of the Patents Act could only be applicable to a product which had been manufactured without the consent of the holder. This was apparent from



the wording of the provision as Section 59 provides that the court may take such corrective measures against a patent protected product that has been manufactured without the consent of the patent holder (Sw. *"ett patentskyddat alster som har tillverkats utan patenthavarens lov"*). Sandoz held that since the manufacture of Fulvestrant Sandoz had not taken place in Sweden, but rather in a country without patent protection and then subsequently imported into Sweden, this manufacture had not required the consent of AstraZeneca. Thus, according to Sandoz, the products had not been manufactured in violation of the provisions of the Patents Act.

The question the PMC had to decide was how the scope of Section 59 should be interpreted. Following the wording of Section 59, the provision requires an unlawful manufacture, i.e. manufacture without the consent of the patent holder. In this case it was apparent that the manufacture was not contrary to the Swedish Patents Act since the absence of patent protection in the country of manufacture meant that it did not per se amount to an infringing act. The question was therefore whether the products manufactured in a country where no patent protection existed could still be considered to fall within the scope of Section 59 of the Patents Act and therefore be ordered for destruction.

Swedish legal commentators have indicated that Section 59 is probably not applicable in a situation as in the present case since the provision requires manufacture without the consent of the patent holder. If no unlawful manufacture has taken place, destruction by order of the court is not possible.[6] However, Article 10 of the Enforcement Directive concerns goods that have been found to be infringing an intellectual property right. It is the finding of infringement that qualifies the application of Article 10, regardless of the character of the infringing act. Thus, there is an apparent discrepancy between Section 59 of the Swedish Patents Act and Article 10 of the Enforcement Directive regarding the basis for the corrective measures according to these respective provisions.

This lacuna was not addressed by the Swedish legislator in the transposition process relating to the Enforcement Directive. On the contrary, it was held that the existing provisions in the Swedish intellectual property statutes regarding products which have been found to infringe an intellectual property right already corresponded to Article 10 of the Enforcement Directive and thus no amendments were proposed.[7] In the present situation, the PMC was thus required to find a suitable interpretation of Section 59 which balanced the an interpretation in conformity with Article 10 the Enforcement Directive without deviating too far from the wording of the Swedish provision, taking the principle of legal certainty into account.

1 59 § 1 st. patentlag (1968:839): "På yrkande av den som har lidit patentintrång får domstolen, efter vad som är skäligt, besluta att ett patentskyddat alster som har tillverkats utan patenthavarens lov ska återkallas från marknaden, ändras, sättas i förvar för återstoden av patenttiden eller förstöras eller att någon annan åtgärd ska vidtas med det. Detsamma gäller i fråga om hjälpmedel som har använts eller varit avsett att användas vid intrånget."

2 See the unofficial translation of the Swedish Patents Act by the Swedish Intellectual Property Office at: https://wwwtest.prv.se/globalassets/dokument/patent/informations-material/the-patents-act---unofficial-translation.pdf.

3 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights.

4 Case PMT 8135-19 of 18 December 2020, Sandoz A/S v. AstraZeneca AB.

5 EP 1 250 138 B2.

6 See, e.g. Holz, Nilsson, The Swedish Patents Act – A Commentary and Comparison with EPC and PCT (Sw. Patentlagen – en kommentar och en jämförelse med EPC och PCT), Jure 2012, p. 287.

7 See Government Bill 2008:09/67, p. 212.

2.2 The Findings

The PMC gave Section 59 a wide scope in line with the wording of Article 10 of the Enforcement Directive. The Court found that since Section 59 is based on the Enforcement Directive, the interpretation must be in line with the wording and purpose of the Directive. The PMC held that according to the relevant provision in the Directive, corrective measures may be taken against products that have been found to infringe a patent right. According to the PMC, the scope of the patent holder's exclusive right also includes import of products to Sweden which may have been manufactured in a country where no patent protection exists. Against this background, the PMC found that Sandoz' import of *Fulvestrant Sandoz* products to Sweden amounted to an infringement of AstraZeneca's exclusive rights. The imported products in question then became *"goods [...] found to be infringing"* in the meaning of Article 10 of the Enforcement Directive.

Thus, the PMC's interpretation clearly related more to the text of Article 10 of the Directive than to Section 59 of the Patents Act. In doing so, the PMC deviated quite far from the wording of the corresponding Swedish provision, which is clearly focused upon the act of manufacturing. The PMC also found that destruction of the products was reasonable under the circumstances, in order not to circumvent the patent protection. AstraZeneca's request for destruction of the Fulvestrant Sandoz products was thus granted.

3. THE PATENT AND MARKET COURT OF APPEAL

3.1 The Reasons

The case was appealed by Sandoz to the PMCA, where the patent was upheld. But the PMCA came to the opposite conclusion regarding the interpretation of Section 59 of the Patents Act, changed the decision of the PMC and revoked the decision to destroy the *Fulvestrant Sandoz* products. The PMCA found that there is a limit to the principle of interpretation in conformity with a directive and stated that too extensive interpretation or interpretation contrary to the wording of the national provision may conflict with the requirement of legal certainty.[8]

The PMCA held that the wording of Section 59 in the Swedish Patents Act clearly states that the goods that may be subject to corrective measures in the case of infringement are patent protected products which have been **manufactured without the consent of the patent holder** (our emphasis). The PMCA stated that the wording of Section 59 expresses that only such goods according to a certain infringing act, i.e. unlawful manufacturing, may be subject to corrective measures. Thus, the provision does not target infringing products in general, but it is specifically stated that it is unlawfully manufactured products that are covered by the provision.

The PMCA then proceeded to a comparison of the corresponding provisions on corrective measures in other Swedish intellectual property statutes and found that the wording of these statutes differs regarding what type of products that may be subject to corrective measures. Some of the statutes focus on the products that are subject to the infringement in question, whereas other statutes (including the Patents Act) state that it is such products that may be tied to a particular act of infringement (e.g. manufacture) that are covered by the provisions of corrective measures. The PMCA held that this difference in wording could not be disregarded in the assessment of whether the conditions for destruction were fulfilled in the present case, regardless of whether the intention of the legislator in the implementation of the Enforcement Directive seems to have been that all goods found to be infringing should be covered by the provisions in question.[9]

[8] See p. 18 of the judgment: "Alltför vidsträckta tolkningar eller tolkningar i strid med den nationella bestämmelsens ordalydelse kan dock strida mot kravet på rättssäkerhet." The PMCA further referred to cases and doctrinal works, e.g. the Court of Justice of the European Union, Judgment of 4 July 2006, Adeneler and Others, C-212/04, ECLI:EU:C:2006:443, paragraphs 108-111.

[9] See Government Bill 2008/09:67, p. 212.

[10] See Government Bill 2008:09/67, p. 212.

[11] The proposal for a new Swedish Patents Act does not address this issue (Swedish Government Official Report 2015:41 Ny Patentlag).

3.2 The Findings

The PMCA went on to state that AstraZeneca's request for destruction was essentially based on Sandoz' infringement of AstraZeneca's patent rights. AstraZeneca had neither claimed, nor invoked any evidence in support of, its assertion that the products in question were unlawfully manufactured. The PMCA held that the scope of application of Section 59 of the Patents Act cannot be extended to also include such goods that are not explicitly covered by the provision in question. The PMCA noted that such an extensive interpretation is neither appropriate nor possible. Thus, since the manufacturing of Sandoz' products was not per se an infringement of AstraZeneca's patent rights, Section 59 could not be applied to grant AstraZeneca's request for destruction of the products in the present situation. The PMCA granted Sandoz' appeal in this part and revoked the PMC's decision pertaining to destruction of the products.

4. COMMENTS

The PMCA's decision draws attention to a conflict between the Swedish provisions on corrective measures and the corresponding provision in Article 10 of the Enforcement Directive. The legislator did not seem to be aware of this problem at the time of implementation of the Enforcement Directive.[10] It has not been discussed in later legislative works either.[11] The decision draws an interesting line between the duty to conform by interpretative means to secondary EU legislation and adherence to the wording of national provisions in a harmonised field of law, in the interest of legal certainty. It seems as if the PMCA has identified a limit to the possibilities of extensive interpretation of national law with the purpose of conforming to EU law. Thus, it presently falls upon the Swedish legislator to attend to the discrepancy between Swedish law and EU law regarding the scope of application for corrective measures in intellectual property law.

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