JÖNKÖPING INTERNATIONAL
BUSINESS SCHOOL
JÖNKÖPING UNIVERSITY

Pharmaceutical patents and generic drugs

When may interim injunctions be issued against an attempt or preparation to offer generic drugs on the market?

Master's thesis in Commercial and Tax law

Author: Björn Rigestam

Tutor: Edward Humphreys

Jönköping 2012-05-14

Master's Thesis in Commercial and Tax law

Title:	Pharmaceutical patents and generic drugs – When may interim injunctions be issued against an attempt or preparation to offer generic drugs on the market?
Author:	Björn Rigestam
Tutor:	Edward Humphreys
Date:	2012-05-14
Subject terms:	Attempt, generic drugs, interim injunctions, offering, Pharmaceutical patents, preparation

---

Abstract

Since the implementation of Directive 2004/48 EC on the Enforcement of Intellectual Property Rights in Sweden there is today a possibility for pharmaceutical companies holding a patent to issue interim injunctions against a generic company on the grounds of an attempt or preparation to a pharmaceutical patent infringement. It has been shown that one of the earliest steps in which a generic company may infringe a pharmaceutical patent is to offer the generic drugs onto the market. However, since the implementation of the attempt and preparation rule in the Swedish Patent Act questions have been raised as to in what stage interim injunctions may be issued against an attempt or preparation to offer generic drugs onto the market made by generic companies. This thesis has therefore intent to investigate at what stage interim injunctions may be applied for against a generic company on the grounds of an attempt or preparation to offer generic drugs.

In the thesis the writer argues that in order for an attempt or preparation to offer generic drugs to exist an overall assessment must be made of the particular situation and that there is no specific principles to follow in order to determine either an attempt or a preparation to offer generic drugs. However, some guidance might be brought from Danish case law in order to establish a preparation to offer generic drugs in Sweden.

Table of Contents

Abbreviations

EU	European Union
IPR	Intellectual Property Right
MPA	Swedish Medical Product Agency
SPC	Supplementary Protection Certificate
TLV	Swedish Dental and Pharmaceutical benefits Agency

1 Introduction

1.1 Background to the problem

Since the implementation of directive 2004/48 EC on the enforcement of intellectual property rights (hereinafter the Enforcement Directive) there is today in all Swedish intellectual property acts a possibility for IPR holders to apply to the court to issue an interim injunction against another party on the basis of an attempt or preparation to an IPR infringement. In relation to patent holders on the pharmaceutical market the rule gives, in accordance with the Swedish Patent Act, the possibility to apply and obtain interim injunctions against another pharmaceutical company on the grounds of attempt or preparation to a pharmaceutical patent infringement. Before the implementation of the Enforcement Directive interim injunctions could only be granted against actual IPR infringements. In the implementation of the directive however Sweden was the only country in EU that explicitly implemented an attempt or preparation rule.

The actors on the pharmaceutical market can roughly be divided into researching pharmaceutical companies which are developing new and improved pharmaceuticals for which they obtain a patent protection and companies who make copies of the original drug (called generic drugs) and whose business strategy is to, once the patent protection on the original drug expires, enter the pharmaceutical market with their cheaper generic drugs.[1]

However, the pharmaceutical market has given rise to many problems and disputes between pharmaceutical companies holding a patent and generic companies. Many of the disputes relates to actions taken by generic companies during the time there is a patent protection on the original drug and whether those actions have constituted an infringement of the company's exclusive right in accordance with the patent. In a report made by the European Commission no fewer than 700 disputes in EU had been registered under 2000-2007 of which 149 of those had been brought to court. In most of the cases it was the company holding the patent who brought the dispute to court.[2]

When it comes to a pharmaceutical company's possibility to enforce their rights against generic companies in accordance with the Swedish Patent Act interim injunctions have

[1] B. Domeij, Läkemedelspatent – Patent på läkemedel i Europa ur ett rättsvetenskapligt och rätssekonomiskt perspektiv, Juridiska Institutionen, Stockholms Universitet, 2008, p.8.

[2] Pharmaceutical Sector Inquiry Final Report – European Commission, 8 July 2009, p.521.

shown to be an effective and powerful tool for pharmaceutical companies in order to combat pharmaceutical patent infringements. The reason for that is that they can be granted quickly in order to stop an alleged infringement of the pharmaceutical patent until the court has made a final decision in the case.

The possibility to issue interim injunctions have shown to be even more important for pharmaceutical companies since the past ten years have brought significant changes to the Swedish pharmaceutical market. In 2002 Sweden established the rule regarding interchangeability and generic substitution which states that all pharmaceuticals which are a part of the Swedish Pharmaceutical Benefits Scheme shall be replaced by the Swedish Pharmacy with the cheapest available pharmaceutical on the market, also called mandatory generic substitution.[3] Further in 2009 Sweden abolished the state pharmacy monopoly with the effect that private actors can establish pharmacies in the country and as of today in comparison to a couple of years ago there are several private actors selling drugs on the pharmaceutical market. This increased activity makes it therefore even more important for pharmaceutical companies to be able to protect their rights in order to prevent generic drugs entering the market before their patent protection expires.[4]

However, since it became a possible to issue interim injunctions against an attempt or preparation to a pharmaceutical patent infringement questions have been raised as to in what stage an attempt or preparation to a pharmaceutical patent infringement should be deemed to exist. Of the different forms a generic company may infringe a pharmaceutical patent it has been shown that the term offering is one of the earliest steps in which a generic company may commit a pharmaceutical patent infringement. Since the implementation of the new rule questions have been raised as to what may constitute such an attempt or preparation by a generic company to offer generic drugs on the market.

In two cases in particular, the Sertraline case in 2008 and the Merck case in 2010, the Swedish court has highlighted that administrative measures such as the application and registration of generic drugs before the patent protection on the original drug had expired could been seen as preparatory actions taken by the generic companies in order to offer the generic drugs on the market. However, the first case was established one year prior to the

[3] 21§, Pharmaceutical Benefits Act (2002:160).

[4] E. Ficks, Seeking Preliminary Injunction for Pharmaceutical Patent Infringement in Sweden – A comparative law analysis of pharmaceutical patent protection and injunction proceedings in the Nordic countries, Roschier, 2009, p. 1.

implementation of the new rule in the Swedish Patent Act and in the second case the court did not further investigate whether such actions could constitute a preparation to a patent infringement, since it was already established that other actions taken by the generic company constituted a complete infringement. The natural question that follows is therefore how an equal situation as of today would be interpreted by the court? It is valuable for pharmaceutical companies holding a patent to know in what stage they can apply for interim injunctions in order to stop generic drugs entering the market and may cause extensive economic damages for the company. It is also important for generic companies in their administrative work before launching their generic drugs onto the market to know what actions that are prohibited to take during the patent protected period. Since no further guidance has been given the legal situation in the area is therefore unclear.

1.2 Purpose

The purpose of this thesis is to investigate at what stage a pharmaceutical company holding a patent may apply for interim injunctions against a generic company on the grounds of an attempt or preparation to offer generic drugs under 1:3§ in the Swedish Patent Act.

1.3 Method

The thesis is divided into three main parts in which different areas related to the problem stated in the thesis are examined independently from each other. The thesis is using a traditional legal method meaning that the legal sources are used in the hierarchy as followed: legislation, preparatory work, case law and literature in the form of books and articles of regarded scholars in the field. The written statutory is primarily used and preparatory work is used in order to interpret and understand the reasoning behind the law.

The thesis is using a descriptive method in the sense that the chapters are built up through a presentation of legal facts. In the end of each chapter the writer´s own thoughts and concluding remarks will be given on the particular area. Since the purpose of this thesis to a large extent is undefined in Swedish law the descriptive chapters of the thesis will consist of an examination and clarification of surrounding areas to the problem which will not directly connect to the purpose of the thesis. In the analysis, however, the facts given in the chapters will be tied together and make the foundation of the analysis and discussion chapter. In this regard the rules set out in the Swedish Penal Code regarding attempt and preparation will be used to a large extent.

Since the rule regarding interim injunctions against attempt or preparation was established in the Swedish Patent Act due to the implementation of the directive 2004/48 EC on the Enforcement of Intellectual Property Rights the basic legal sources in chapter 4 will focus on the directive 2004/48 EC on the enforcement of intellectual property rights, current legal law stated therein and Swedish preparatory work to the implementation of the directive.

Further, the thesis is based on a high degree on case law. Although preparatory work is a useful guidance on how to interpret and understand the law only general guidelines can be discerned from source. By analyzing the court's reasoning in case law a deeper examination of the particular area is possible and is also of importance in order to see in which direction the legal position of the problem is going.

However, when it comes to the establishment of an attempt or preparation to offer generic drugs no Swedish case law is available and Swedish legislation does not provide anything more than general principles on how attempt and preparation would be established in accordance with the rules set out in the Swedish Penal Code. Further, Sweden is the only country in the EU that has an explicitly stated attempt and preparation rule. In order to investigate how an attempt or preparation could be established in Sweden references will be made to Denmark and established principles in Danish case law. This is used in order to see whether some guidance could be used on how to interpret an attempt or preparation to offer generic drugs in Sweden. The reason for using Denmark is particular because Denmark has established cases when interim injunctions may be issued against a generic company in the situation of an imminent pharmaceutical patent infringement, in other words before an actual infringement occurs. Further, Denmark and Sweden has to a large extent uniform Patent Acts due to the Nordic patent reform which was established in the 1960s.[5] In this regard Denmark will be used in the analysis as a reference point and a comparison will be made between the concept of an attempt or preparation and the established principles of an imminent pharmaceutical patent infringement in Danish case law. In order to find Danish sources I have especially used the Danish databases "UfR Online" and "Rettsinformation.dk". In this context it should, however, be mentioned that the sources have been in the Danish language which have made the interpretation of the sources somewhat complex. The legal weight of the sources is therefore slightly lower in comparison to other sources in the thesis.

[5]NU 1963:6.

Finally, it will be pointed out that since the purpose of this thesis to a large extent is undefined in Swedish law the analysis will mainly consist of the writers own thoughts and opinions based on the legal facts stated in the thesis.

1.4 Delimitation

There are many ways a generic company may infringe a pharmaceutical patent in accordance with the Swedish Patent Act. However, the thesis will only focus on the term offering as a pharmaceutical patent infringement in the Swedish Patent Act. Since an offering of the generic drugs is one of the most common ways in which a generic company may infringe a pharmaceutical patent and is also the most widely used concept of the infringement forms stated in the Swedish Patent the key question of this thesis will be answered by focusing on the term offering. However, the other infringement forms will be briefly highlighted in order to give the reader information regarding patent infringement in general. Further, an investigation of what would constitute an attempt or preparation in relation to all infringement forms stated in the Swedish Patent Act would be extensive for this work.

Since the implemented rule into the Swedish Patent Act was aimed at interim injunctions as a tool against attempt or preparation to a patent infringement this thesis does not intend to highlight and examine other forms of sanctions stated in the Swedish Patent Act. Although that would be interesting the work will be far too extensive and it will not be needed in order to answer the purpose of this thesis.

Further this thesis does not intend to highlight all kinds of administrative rules relating to the possibility to issue interim injunctions in Sweden and Denmark. Further, although the criterions for issuing interim injunctions in Sweden and Denmark will be highlighted no deep examination will be made of the individual criterion set out in the Swedish Patent Act and the Danish "Retsplejeloven". The reason for that is that the main purpose of the thesis is not to examine the concept of interim injunction in itself but how to establish an attempt or preparation to offer generic drugs.

Several member states within the EU have developed practices on how to issue interim injunctions against a generic company before an actual pharmaceutical patent infringement has occurred. Although a highlighting of those countries could be of interest for this thesis only Denmark will be used as a reference since an examination of other countries as well would be far to extensive for this thesis.

1.5 Outline

Chapter 2 intends to give the reader a background to the pharmaceutical market and the relation between patent protected pharmaceuticals and generic drugs. This chapter also intends to highlight the effect of generic drugs entering the market in order to demonstrate the harmful damages an infringing generic drug may cause a pharmaceutical company holding a patent.

Chapter 3 consists of a legal background in which patent infringement in general and the concept of offering is presented. The chapter further highlights the concept of injunctions and especially interim injunctions in the Swedish Patent Act in order to give the reader a background as to why interim injunctions may be an effective tool to stop patent infringements. Further, an examination will take place of the criteria which have to be fulfilled in order to issue an interim injunction.

Chapter 4 focuses on the directive 2004/48 EC on the enforcement of intellectual property rights and the implementation of the directive into the Swedish Patent Act. This chapter especially seeks to examine the stated rules in the directive regarding a patent holder's right to apply for interim injunctions against imminent IPR infringements. Further, this chapter intends to highlight the Swedish legislators' decision to implement the interim injunction rule against attempt or preparation to a patent infringement and how attempt and preparation would be established in contrast to the rules set out in the Swedish Penal Code.

Chapter 5 intends to investigate what constitutes an actual offering made by a generic company and what exceptions to patent infringement that are stated in the Swedish Patent Act. In this regard current Swedish case law will be examined in depth in order to establish principles relating to the concept of an offering. Further this chapter intends to establish the borderline between actions taken by generic companies that will be seen as an offering of the generic drugs and what actions that do not constitute an offering of the drugs in accordance with the Swedish Patent Act.

Since there are only general guidelines in Swedish legislation and no Swedish case law on how to establish an attempt or preparation to offer generic drugs chapter 6 intends to examine how Denmark have applied interim injunctions against generic companies before an actual infringement of the pharmaceutical patent has occurred (in the case of an imminent pharmaceutical patent infringement). In this regard two Danish cases will be examined in

order to establish principles that might be used as a reference point in order to establish an attempt or preparation to offer generic drugs in Sweden.

Chapter 7 will consist of an analysis of the given facts and the concluding remarks stated in chapter 4, 5, and 6 especially. Chapter 7 intends to tie the chapters together and through the analysis put the definitions of an attempt and preparation stated in the Swedish Penal Code in relation to the principles regarding offering established in Swedish case law. In this regard attempt and preparation will be examined individually in the analysis. As a last part in the analysis references will be made to the established principles in the two Danish cases regarding an imminent pharmaceutical patent infringement. In this section a comparison will be made between attempt and preparation and an imminent pharmaceutical patent infringement in Denmark and whether some of the established principles may be used as guidance in order to establish an attempt or preparation to offer generic drugs in Sweden.

2 Pharmaceutical patents and generic drugs

2.1 Pharmaceutical patents

As within most areas there are possibilities within the pharmaceutical market for researching pharmaceutical companies to patent their inventions. The basic rules to patent an invention are stated in the first paragraph in the Swedish Patent Act. Anyone who has made an invention and which could be industrially applicable may apply for a patent and by that have an exclusive right to commercially exploit the invention.[6] One reason to give an inventor an exclusive right to the invention is that there is an interest within societies that there is a continued development of new inventions since technical development many times is a result of patented inventions.[7] The possibility to patent inventions also stimulates new inventions because there is an economic aspect of having a monopoly to sell and promote the invention during a certain time. This is especially very important for researching pharmaceutical companies.[8]

When talking about pharmaceutical patents it is of importance to highlight and differentiate pharmaceutical product patents and process patents. Regarding product patents the rightholder has been approved a patent on the chemical compound of the pharmaceutical (the product in itself) and in which a chemical formula is described in the patent claim. When it comes to process patents within the medical area is usually the process in which the pharmaceutical is manufactured that is patented.[9]

There is probably no other industrial sector where the possibility to patent an invention is as important as on the pharmaceutical market. Domeij highlights in his doctoral dissertation from 1998 that from an interview with the pharmaceutical industry`s business leaders over 60 % of the company's latest innovations would not have been a reality if there had not been a possibility to patent the innovations. On other markets the same was just under 7 %.[10] The economic aspect for pharmaceutical companies to patent their pharmaceutical and have a monopoly to sell and promote it during a certain time can be derived from the

[6] 1:1 §, Swedish Patent Act (1967:837).

[7] Prop. 1993/94:22, p. 24.

[8] B. Domeij - Läkemedelspatent, p.1.

[9] B. Domeij - Läkemedelspatent, p.91.

[10] B. Domeij - Läkemedelspatent, p.1.

amount of money the company has put in into research and development of the pharmaceutical. The average cost to develop a new pharmaceutical from research to market approval is said to be 1.3 billion USD and the development time of the pharmaceutical is between 10-12 years.[11] Since a lot of the company's capital has been invested in research and development of new and improved pharmaceuticals the patent system gives the company an opportunity to earn back the capital that they have invested.[12]

However, the original protection time for a patent is twenty years from the day the application for a patent was made.[13] In most other industries a product can be sold at the same time an application for a patent has been made. However, when it comes to pharmaceuticals the main rule is that they are not allowed to be sold until a market approval has been obtained. In order to obtain such an approval the pharmaceutical has to go through numerous tests in order to fulfill the regulations set out in the area. Such procedure takes several years and it is not unusual that it takes up to twelve years from the day the application for a patent was made until a market approval has been obtained. At that point only eight years remains on the patent protection time and in which the company with the monopoly is able to sell the pharmaceutical.[14]

Although there is a heavily reduced effective patent protection period when it comes to pharmaceuticals there is, since 1992 and with an adoption of a new regulation within EU in 2009, a possibility to extend the protection time on pharmaceuticals with a so called Supplementary protection certificate (SPC).[15] The idea with the regulation was to reduce the problem with the short effective patent protection period on pharmaceuticals and make a common system for an extension of the protected time for pharmaceuticals in all member states of the EU. The protection time can be extended by a maximum of five years. The extended period is established on the basis of how long it has taken to get a market approval for the pharmaceutical.[16] However, despite the possibility to obtain a SPC protection

[11] LIF:s FOU- enkät 2010, rapport 2011:1, Mars 2011 p.6.

[12] Prop. 1993/94:22, p. 24.

[13] 4:40 §, Swedish Patent Act (1967:837).

[14] Prop.1994/95:86, p. 10-11.

[15] Council Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products.

[16] Prop. 1994/95:86, p. 11.

on the pharmaceutical the period in which a pharmaceutical can be sold is to a large extent shorter than in other areas.

In many cases it is later shown during the studies on the pharmaceutical that is has unacceptable side effects, not enough biological effect or is too expensive to develop. In other words a pharmaceutical company can put many years and capital into research and development of a particular drug and in the end will not be able to sell it. It has been appreciated that only 2-5 percent of all published pharmaceutical patent applications actually later will protect a selling product.[17]

2.2 Generic drugs

Generics are drugs in which the biologically active substance already has been introduced on the market.[18] According to the Swedish Medical Product Act the definition of a generic drug is that it is a pharmaceutical which has the same qualitative and quantitative composition in active substances and the same form and bioequivalence as the reference drug.[19] Reference drug in this case means the original drug for which there is or have been a patent protection. In other words, generics are copies of the original drug. The idea with the producers of generic drugs is that as soon as possible after a patent protection on a pharmaceutical has expired to introduce the generic drug on the market. Generic drugs are relatively inexpensive in comparison to original drugs since the generic companies have not needed to put the same amount of capital into research and development of the generic drug. The result is therefore that after the expiration of the patent protection on an original drug other players will show up on the pharmaceutical market and sell identical generic drugs at a cheaper price.[20]

2.3 The effects of generic drugs entering the market

Since a generic drug can be sold at a much lower price than the original drug once a generic drug has entered the pharmaceutical market it will affect the selling of the original drug. An example of how fast a generic drug can enter the market after the patent protection had expired is when the protection on the drug Zantac expired in Germany no less than fifteen

[17] B. Domeij – Läkemedelspatent, p.1.

[18] B. Domeij – Läkemedelspatent, p. 8.

[19] 1§ paragraph 5, Swedish Medical Product Act (1992:859).

[20] B. Domeij – Läkemedelspatent, p.8.

generic drugs was out on the market and immediately took half of Zantac´s market shares.[21] According to studies made on the area during the first year after the patent on a pharmaceutical has expired the original pharmaceutical company market share is approximately decreasing with 35 percent. The second year it will approximately decrease with 50 percent.[22] When the patent protection on an original drug has expired that is although something a pharmaceutical company has to accept.

However, in cases where a generic product is being released during the time there is a patent protection on the original drug it may cause immediate economic damage for the patent holder and even make it impossible for the company to recover lost market shares and profits.[23]

[21] B. Domeij - Läkemedelspatent, p.8.

[22] B. Domeij - Läkemedelspatent, p.8.

[23] R. Hilli, T. Groop - Imminent threat of infringement, Nordic States: biotechnology, July/August 2008, p. 133.

3 The concept of Interim injunctions

3.1 Introduction

This chapter intends to highlight the concept of injunctions and especially interim injunctions in the Swedish Patent Act in order to give the reader a background as to why interim injunctions may be an effective tool to stop patent infringements. Further, an examination will take place of the criteria that have to be fulfilled in order to issue an interim injunction.

3.2 Patent infringement in general

1:3 § of the Swedish Patent Act regulates what forms of exploitation of a patented invention that constitutes a patent infringement. There are especially four types of actions that constitute an exploitation of the invention. The rule in 1:3 § states that the exclusivity to the patent gives no one the right without the consent from the patent holder to:

1. Make
2. offer
3. put on the market; or
4. use

a product protected by the patent or to import or possess such products for those purposes.[24]

Further 1:3 § states that it is further prohibited:

"to using a process which is protected by the patent or, knowing, or it being obvious from the circumstances that the use of the process is prohibited without the consent of the proprietor of the patent, offering the process for use here in Sweden."[25]

It is also prohibited:

"to offering, putting on the market or using products made by a process protected by the patent or importing or possessing the product for these purposes".[26]

All the mentioned situations referred to in 1:3 § constitute different types of patent infringement. The first prohibition refers to infringements on a protected product patent.

[24] 1:3 § first paragraph point 1, Swedish Patent Act (1967:837).

[25] 1:3 § first paragraph point 2, Swedish Patent Act (1967:837).

[26] 1:3 § first paragraph, point 3, Swedish Patent Act (1967:837).

The second prohibition refers to infringements on a protected process patent while the third prohibition states the concept of indirect product protection.[27]

1:3 § point 1 refers to situations of a direct infringement of a product patent. That is to make, offer, putt on market or use a patent protected product or to import or possess the same. The listed exploitations of the invention are a general formulation and shall be seen as to include all possible commercial use of the patented invention.[28] The listed exploitations are only examples and many different situations of direct patent infringements can be included in the article.[29]

Article 1:3 § point 2 is applicable to direct infringement of a protected process. As with the case of direct infringement of a protected product the same regarding using and offering the process will constitute a direct infringement if the protected process is offered in Sweden. The first two situations are to be seen as direct infringements since they apply directly to the protected patent whether it is a product or a process that has been protected.

The third alternative in which a patent infringement may be relevant is in cases of indirect infringement or indirect product protection for the rightholder. If someone is offering, putting on the market or using a product that has been manufactured through a protected process or importing or possessing the product it will constitute a patent infringement. When it comes to offering a protected process stated in point 2 the offering has to be made within Sweden. However, when it comes to offering a product that has been manufactured through a protected process there is not a need that the offering has been made in Sweden. It is therefore irrelevant whether the offering of the product is meant to be used in Sweden or abroad.[30]

3.3 The concept of offering

When it comes to the four exploitations of a patented invention stated in the Swedish Patent Act, namely to make, offer, put on market or use a patent protected invention or importing or possessing the same offering of generic drugs is probably the earliest action that

[27] L. Jonshammar - Karnov Internet, Constitutional commentary to the Swedish Patent Act (1967:837), 1:3 § first paragraph, point 3, number 26, last visited 9th of march 2011.

[28] Prop. 1977:78, part A, p. 327.

[29] Prop. 1977:78, part A, p. 327.

[30] L. Jonshammar - Karnov Internet, Constitutional commentary to the Swedish Patent Act (1967:837), 1:3 § first paragraph, point 3, number 26, last visited 9th of march 2011.

could constitute a pharmaceutical patent infringement.[31] There is however a possibility that both making and using of the generic drugs may occur before any offering has taken place but that such actions may have been committed abroad. Further an offering of the generic drugs is something that would occur before the generic drugs have been put on the market for selling. An offering in this case may therefore be seen as a preparatory action taken by the generic company in order to put the generic drug onto the market but is also to be seen as an independent action which constitutes a patent infringement in accordance with the Swedish Patent Act.[32] Further, an offering could also exist before any import of the generic drugs has been made into the country. In this regard a generic company may offer the generic drugs to different parties and then import the products.

3.4 Why injunctions?

Injunction is an action that today is permitted in all Swedish IPR laws. Injunctions as a tool against patent infringements has been discussed in Sweden since the Swedish Patent investigation in 1943 but it was not until 1986 the possibility to issue injunctions were implemented into the Swedish Patent Act.[33]

The reason to implement the rules regarding injunctions into the Swedish Patent Act was that the general view was that the measures that could be taken by a patent holder in cases of an alleged infringement of the patent rights were not enough. This was especially the case when the rightholder was economically inferior to the infringer. To have the possibility to issue a prohibition in combination with a penalty fee against a patent infringer could therefore be an effective tool to stop an infringement.[34] Another reason for such a prohibition was that a patent holder when applying for an injunction against an alleged infringer does not need to show that the infringement is made by intention or negligence by the infringer, which has to be proven when it comes to other forms of sanctions stated in the Swedish Patent Act such as penalties and compensation for damages. Further the patent holder does not need to show any evidence of the harmful damages the infringement give rise to. The only thing the patent holder needs to show is that there is a patent infringe-

[31]E. Ficks, T. Groop – Interimistiska förbud vid intrång I läkemedelspatent, Nordiskt Immateriellt Rättsskydd/Nordic Intellectual Property Law Review, no. 2/2009, p. 123.

[32]E. Ficks, T. Groop – Interimistiska förbud vid intrång I läkemedelspatent, p. 122.

[33] Prop. 1985/86:86.

[34] Prop. 1985/86:86, p. 27.

ment in an objective sense.[35] On those grounds the possibility for a patent holder to apply for injunctions against an alleged infringer and adjust the penalty fee depending on the situation could therefore deter the alleged infringer to continue with the infringement.[36]

3.5 Interim injunctions stated in the Swedish Patent Act

The interim injunction is a procedural precaution which a rightholder can use during a pending process in the court or during a limited time with the effect that a prohibition is being issued against an infringing party. During the time the prohibition applies the alleged infringer has to stop its activities for which the prohibition is aimed for or otherwise a penalty of fine will be raised.[37]

In the Swedish Patent Act the possibility to apply for an interim injunction against another party is stated in 9:57b § second paragraph:

"If the plaintiff shows it to be probable that an infringement is occurring and if it may reasonably be feared that the defendant will, by continuing the infringement, reduce the value of the exclusive right to the patent, the Court may impose a prohibition on penalty of a fine for the period until the case has been finally decided or some other decision has been made."[38]

Further in 9:57b § third paragraph it states:

"The first and second paragraphs should also be applied as to attempt or preparation to an infringement"[39]

The rule therefore gives a patent holder the possibility to apply to the court to issue an interim injunction against another party to stop its activities until the court have made a final decision in the case. As seen above (and which will be examined in this thesis) an interim injunction may also be obtained against someone that is attempting or preparing to infringe the patent.

---

[35] Prop. 1985/86:86, p. 27.

[36] Prop. 1985/86:86, p. 27.

[37] D. Ramsjö – Proportionalitetsprövningen vid interimistiska förbud i immaterialrätten, 1/2009,p.77. http://www.juridiskpublikation.se/2b/?id=85.

[38] 9:57b § second paragraph, Swedish Patent Act (1967:837).

[39] 9:57b § third paragraph, Swedish Patent Act (1967:837).

In order to issue an interim injunction especially three criterions has to be fulfilled. First of all the applicant has to show a probability that an infringement is at hand. A probability that an infringement is at hand comprises a lower evidentiary that is usually set out in order to deliver a judgment in civil cases.[40] When it comes to the probability criterion the same as with ordinary injunctions is applicable namely that the applicant only has to show that there is a patent infringement or an attempt or preparation to the same in an objective sense. On those grounds the applicant therefore does not need to show any intention or negligence by the other party.[41]

If the applicant has shown a probability, the applicant further has to show a reasonably fear that the defendant will, by continuing the infringement, reduce the value of the exclusive right to the patent. In this regard the applicant does not need to show that the other party have had an intention to reduce the value of the exclusive right, it is enough that the infringement can have that effect if it is continued. In other words the situation handles a future damage.[42]

Finally in order for an interim injunction to be granted the applicant has to put security for the damage which an interim injunction may cause the other party. In cases of interim injunctions the court may in the main proceedings come to the conclusion that there has not been any infringement of the patent. Since the interim injunction in such cases have prohibited the defendant to do certain actions which in the end was shown not to be a patent infringement the applicant therefore often needs to put economic security for the damages the interim injunction may have caused the defendant if the actions later was shown not to constitute a patent infringement.[43]

Although an interim injunction only is a preliminary decision taken by the court it has been shown that both globally and in Sweden interim injunctions often is the end point in court proceedings since the parties many times chooses to solve the dispute through negotiations instead. Therefore the interim injunction works as a hint of the courts position in the case

[40]D. Ramsjö – Proportionalitetsprövningen vid interimistiska förbud i immaterialrätten, 1/2009, p.80. http://www.juridiskpublikation.se/2b/?id=85.

[41] D. Ramsjö – Proportionalitetsprövningen vid interimistiska förbud i immaterialrätten, 1/2009, p.80. http://www.juridiskpublikation.se/2b/?id=85.

[42] D. Ramsjö – Proportionalitetsprövningen vid interimistiska förbud i immaterialrätten, 1/2009,p.80. http://www.juridiskpublikation.se/2b/?id=85.

[43] 9:57b § third paragraph, Swedish Patent Act (1967:837).

and the companies decides to solve it in another way instead. In that matter the interim review made by the court could be seen as a "fast proceeding" in disputes regarding patent infringements.[44] When it comes to the three criterions stated above it has been shown that it is most often the question whether a probability exist or not that determines whether interim injunctions would be granted.[45]

3.6 Concluding remarks

As shown above three criterions have to be fulfilled in order to issue an interim injunction against an infringement. First of all there has to be a probability of an infringement, second of all the applicant has to show a reasonably feared that the defendant will, by continuing the infringement, reduce the value of the exclusive right to the patent. Third the applicant has to put economic security for the damages the interim injunction may have caused the defendant if the actions later were shown not to constitute a patent infringement. It has been shown that the probability criterion are often the one that in the end determines whether an interim injunction would be granted or not during the court proceedings. In the case of showing a probability the applicant only has to show that there is an infringement in an objective sense. The applicant therefore does not need to show any intention or negligence by the infringer. Since the implementation of the attempt or preparation rule the same criteria should also be applicable to attempt or preparation to a patent infringement.

[44] B.Domeij – Fokus på patenträtten, p.83.

[45] B. Domeij, Fokus på Patenträtten – En introduktion till patenträtten, 1997, Brand Eye AB, Stockholm, p. 82.

4 The implementation of the Enforcement Directive

4.1 Introduction

In order for the reader to get an understanding of the implemented rule in the Swedish Patent Act regarding interim injunctions against attempt and preparation for a patent infringement this chapter intends to highlight the Enforcement Directive and its rules regarding interim injunctions as a tool against imminent patent infringements. This chapter further intends to highlight the Swedish legislators` reasoning in the implementation of the directive and how an attempt and preparation would be established.

4.2 Why the directive?

The Enforcement Directive was approved by the European parliament and the council of the European Union in April 2004.[46] The member states of the European Union had to bring into force the laws, regulations and other administrative provisions necessary to comply with the directive no later than 29 April 2006.[47] The main reasons for the implementation of the directive was that intellectual property protection throughout the member states of the European Union was an essential part for success for companies on the market and that unified rules on how to enforce their rights was needed in order to allow the inventor or creator of the right to derive a legitimate profit from the invention or creation.[48] Before the initiative to the Enforcement Directive there were several provisions on the means of enforcing IPRs already existing and implemented in all member states. The Agreement on trade-related aspects of intellectual property (The TRIPS agreement) was ratified in 1994 and contains provisions on enforcing intellectual property law at an international level and is implemented in all member states and other conventions such as the Paris convention for the protection of industrial property[49]. Although there were several international agreements on the enforcement of IPRs, especially the TRIPS agreement, it was determined that there were still major differences between the member states in the means of enforcing IPRs. The Commission noticed amongst other things that the rules and arrangements regarding applying for injunctions against infringers differed considerably be-

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

[47] Directive 2004/48/EC, art. 20 Paragraph. 1.

[48] Directive 2004/48/EC, preamble 2.

[49] Directive 2004/48/EC, preamble 4-6.

tween the member states.[50] According to the Commission, these major differences in the means of enforcing IPRs led to loss of confidence within business areas in the internal market and which affected the investment in innovation and creation. The objective of the Enforcement Directive was therefore to approximate the legislative systems as to ensure a high, equivalent and homogenous protection throughout the European Union.[51]

4.2.1 The scope

The enforcement directive is applicable to all intellectual property infringements that derive from community law or the national laws of the member states.[52] Further on, the rules set out in the Enforcement Directive are to be seen as a reinforcement of the rules set out in the TRIPS agreement.[53] However, the directive should not affect the member state`s international obligations derived from the TRIPS agreement and other international conventions.[54] The Enforcement Directive is a minimum directive meaning that the goal and purpose of the directive is binding for the member states but leaving the national authorities to decide the choice of form and methods of the execution of the rules set out in the directive. This also means that member states can apply more favorable rules for a rightholder than the directive states.[55]

4.2.2 Principles stated in the directive

The directive gives the member states several principles to follow when it comes to the execution of the rules set out in the directive. The procedural principles in the directive states that the measures, procedures and remedies shall be fair and equitable and shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays. The procedure shall in other words be fair, cheap and fast. Principles related to the use of the sanctions states that they shall be effective, proportionate and dissuasive and shall be applied in such a manner as to avoid any barriers to trade within the internal market. All principles must be followed when implementing the directive and in the execution of the

[50] Directive 2004/48 EC, preamble 7 and COM (2000) 789, Communication from the Commission to the Council, the European parliament and the Economic and Social Committee, Follow-up to the Green Paper on combating counterfeiting and piracy in the single market p.2.

[51] Directive 2004/48 EC, preamble 9-10.

[52] Directive 2004/48 EC, article 2 paragraph1.

[53] M. Norrgård - Immaterialrättens Sanktionssystem och Enforcement-direktivet, NIR 2004, p. 444.

[54] Directive 2004/48 EC, article2 paragraph 3b.

[55] Directive 2004/48 EC. art. 2 Paragraph 1.

rules in the judicial procedure in every member state. Further, all measures taken by the national courts in the member states should be determined in each case. That means that the national courts should look at the specific characteristics of each case, including the different characteristics in the different types of the IPR and, where appropriate, if the infringement has been intentional or unintentional.[56] This probably means in a simplified sense that the sanctions should be determined, after an examination, in every case where a rightholder have applied for a sanction against an alleged infringer.

4.2.3 Injunctions against imminent IPR infringements

The article of interest for this paper and which will be examined below is the one that regulates the possibility for an intellectual property right holder to apply for interim injunctions against an alleged intellectual property infringer.

Article 9 in the Enforcement Directive gives the rightholder a possibility to apply for an interim injunction against an alleged infringer. As with the general purpose of interim injunctions the rules stated in article 9 should be applied as a preliminary action to stop an alleged infringement of an IPR until a final decision of the case has been made in the court proceedings.

Art. 9.1a of the Enforcement Directive states that:

"Member states shall ensure that the judicial authorities may, at the request of the applicant: Issue against the alleged infringer an interlocutory injunction intended to prevent any imminent infringement of an IPR, or to forbid, on a provisional basis and subject, where appropriate, to a recurring penalty payment where provided for by national law, the continuation of the alleged infringements of that right"

Further in art. 9.3 It is stated that:

"The judicial authorities shall, in respect of the measures referred to in paragraphs 1 and 2, have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the rightholder and that the applicant`s right is being infringed, or that such infringement is imminent"

[56] Directive 2004/48 EC article 3 paragraphs 1-2, see also. M. Norrgård - Immaterialrättens sanktionssystem och Enforcement-direktivet, p. 445.

Thus, the rule states that it is up to the authorities in the member states to ensure that there is a possibility for an IPR holder to apply for an interim injunction against an alleged infringer in the case to prevent any imminent infringement of the IPR. According to article 9 there are in particular three ways on how an interim injunction can be issued. First of all it can be issued in cases to prevent any imminent infringement of an IPR, or second of all temporally prohibit, if necessary together with a fine if that is prescribed in the national law, the continuation of the alleged infringement and third to make such continuation subject to guarantees of remuneration to the holder of the IPR.

Art. 9.3 further states that in order for an interim injunction to be issued the applicant have to provide a certain degree of evidence that the applicant is the right holder of the IPR and that the IPR is being infringed or that the infringement is imminent.

4.3 The implementation of the directive in Sweden

The Enforcement Directive had to be implemented by all member states no later than 29 of April 2006. Sweden failed heavily in this regard and in May 2008 the ECJ convicted Sweden of violating the convention on the grounds that the implementation of the Enforcement Directive had not occurred on time.[57] However, it was not until 24 February 2009 that the Swedish parliament voted for the implementation of the directive to enter into force as of 1 April 2009.

As shown in chapter 3.5, before the implementation of the directive there was already a possibility in the Swedish Patent Act to issue interim injunctions against a patent infringer.[58] In cases of final injunctions the rightholder could apply to the Swedish court to issue a final injunction in order to stop an ongoing patent infringement. There was also a possibility for a rightholder to apply for an interim injunction to stop an ongoing patent infringement until the court had made a final decision in the court proceedings. Therefore, in order to apply for either final injunctions or interim injunctions there had to be an actual infringement of the patent right.[59]

Regarding interim injunctions in the Enforcement Directive it did not give any further guidance on how to interpret the word "imminent" and in what situations a rightholder can

[57] The Commission of the European Communities vs. the Kingdom of Sweden, C-341/07, 15 May 2008.

[58] 9:57b § first and second paragraph, Swedish Patent Act (1967:837).

[59] Prop. 2008/09:67, p. 186.

claim that there is an "imminent" infringement of an IPR. As described under chapter 4.2.2, the preamble to the Enforcement Directive states that every sanction issued by the court has to be determined in each specific case. The national courts also need to require the applicant to show sufficient degrees of evidence that an infringement of the right is "imminent". Since the directive gave the member states the freedom to decide the form and methods of the implementation and execution of the rules set out in the directive it was therefore also up to the member states and national courts to interpret the wording "imminent" infringement.

4.3.1 The Swedish interpretation of "imminent"

In the Swedish implementation of article 9 it was found that there was no common definition on what constitutes an "imminent" infringement and that there was no general obligation as to ensure interim injunctions against "imminent" infringements.[60] In the preparatory work it was stated that a reasonable interpretation of "imminent" was that the national rules gave the possibility to issue interim injunctions even before an actual infringement had occurred and it was up to national law, having regard to the principle of proportionality stated in the preamble to the directive, to more closely decide conditions of when an "imminent" infringement existed.[61] In the preparatory work it was stated that in accordance with the Swedish law today there was a possibility to issue final and interim injunctions against completed infringements but there was no possibility to do so if an "imminent" infringement was regarded to be a situation which took place before an actual infringement has occurred.[62]

In the preparatory work the Swedish legislator pointed out that there already existed other sanctions in the Swedish intellectual property laws against attempts or preparations for an intellectual property infringement.[63] For example, a complete infringement committed by intention or negligence is a penalized action in the Swedish Patent act and also criminal attempts and preparations for the same constitutes a penalized action in accordance with the rules set out in the Swedish Penal Code.[64] However it was pointed out that at this point,

[60]E. Ficks, T. Groop – Interimistiska förbud vid intrång I läkemedelspatent, p. 132.

[61] Prop. 2008/09:67, p. 200.

[62] Prop. 2008/09:67, p. 200.

[63] Prop. 2008/09:67, p. 189 and DS 2007:19, p. 225.

[64] E. Ficks, T. Groop – Interimistiska förbud vid intrång i läkemedelspatent, p. 133.

under current law, there was no possibility to issue final injunctions and interim injunctions on the grounds of an attempt or preparation to an infringement.[65] In the preparatory work both attempts and preparations was to be seen as actions taken place before an actual infringement had occurred and such situations of initiated attempts or preparations to infringements could be seen as equal to the situation of an "imminent" infringement. It was argued that if there was a possibility to issue injunctions already at the attempt and preparation stage it would prevent completed infringements to occur.[66] It was further stated that if there would be a possibility to issue injunctions against attempt or preparation to an infringement that would be an effective weapon against counterfeiting and piracy at the market, especially in cases where the infringement would cause major damages to the rightholder. Further, it would result in that the intellectual property legislation would be more consistent since other security measures and penalties were applicable on attempt or preparation to an infringement. Also in cases of interim injunctions at least that would to a greater extent be an effective weapon to prevent future infringements to occur.[67]

However, article 9 and the "imminent" infringement scenario was only addressed to situations of interim injunctions. Regarding final injunctions article 11 stated that such measures may be issued against an infringer in cases of prohibiting the continuation of the infringement. Final injunctions were therefore applicable only in situations where there had been an initiated or complete infringement.[68] The Swedish legislator stated that the idea of interim injunctions was that it was as a preliminary measure until a final decision of the case had been made in the court and that the idea and goal with interim injunctions was to secure a future enforcement of a judgment in the court. It was therefore not possible to give an interim injunction on certain grounds that could not be given a final decision.[69] In the implementation of the directive the Swedish legislator therefore decided that also final injunctions could be issued on the grounds of attempt or preparation to an infringement.

[65] Prop. 2008/09:67, p. 189, 200.

[66] Prop. 2008/09:67, p.200.

[67] Prop. 2008/09:67, p. 189 and DS 2007:19, p. 226.

[68] Directive 2004/48 EC, article 11.

[69] Prop. 2008/09:67, p. 189.

4.3.2 Attempt and preparation vs. imminent

It has been shown that Sweden was the only country in the EU that implemented the possibility to issue interim injunctions against an attempt or preparation to an IPR infringement. The idea in giving the possibility to issue interim injunctions in an imminent situation was that it should give a rightholder the possibility to stop another party when there was an immediate risk for an IPR infringement and that the situation therefore was extremely urgent.[70] However, the European observatory highlighted Sweden in its report and stated that an attempt or preparation to an infringement covers more than an imminent infringement. The report further stated that an attempt or preparation to an infringement may exist before a situation is extremely urgent and Sweden therefore went further than other countries in the implementation of the rule.[71]

4.3.3 Attempt in the Swedish Penal Code

As shown previous, the Swedish legislator decided to interpret an imminent infringement as equal to attempt or preparation to an infringement. Attempts and preparations are not to be seen as a common concept but rather two different actions that should be examined separately from each other.[72] It is off course possible that an infringer could do both attempt and preparation for an infringement at the same time but the meaning of the two is different.

As described in the previous chapter a completed infringement committed by intention or negligence constitutes a penalized action in the Swedish Patent Act and attempts or preparation constitutes the same a penalized action in the Swedish Penal Code.[73] In the constitutional commentary to the Swedish Patent Act it states that in order to issue injunctions against an attempt to a patent infringement the requisites for attempt stated in paragraph 23:1§ Swedish Penal Code have to be fulfilled.[74] However, it is further stated that the

[70] European Observatory on Counterfeiting and Piracy – Injunctions in Intellectual Property Rights, p1.

[71] European Observatory on Counterfeiting and Piracy – Injunctions in Intellectual Property Rights, p 21.

[72] See 9:57b third paragraph, Swedish Patent Act (1967:837), attempt *or* preparation to an infringement.

[73] 9:57§ second paragraph, Swedish Patent Act (1967:837).

[74] Prop. 2008/09:67, p. 287 and P. Sande – Constitutional commentary to the Swedish Patent Act, 9:57b § third paragraph, number 210, Karnov, last visited 18th March 2012.

rightholder should not need to prove any intention or negligence by the infringer. [75] 23:1 § in the Swedish Penal Code it states that:

"A person who has begun to commit a crime without bringing it to completion, shall in cases where specific provisions exist for the purpose, be sentenced for attempt to commit crime if there was a danger that the act would lead to the completion of the crime or such danger had been precluded only because of fortuitous circumstances". [76]

In order for an attempt to exist it is generally demanded that the person has started the execution of a particular crime. Such an execution could exist when it has been shown that the person has left the planning stage. It is further stated that an attempt should exist when the person has done everything according to the crime plan in order for the crime to be completed if the situation continues to develop in the way that he has imagine, so called complete attempt.[77]

As an example of such an attempt is that someone has prepared a false tax return and further posted it to the tax authorities.[78] In this regard the person has done everything according to the crime plan in order for the crime to be completed if the situation continues to develop in the way that he has imagined. Once the false tax return has arrived at the tax authorities a complete crime has been made.

An attempt could also be at hand in cases when something more needs to be done. However, the remaining thing has to be in a close connection to the things that has already been done, both when it comes to the action in itself but also in close connection in time.[79]

4.3.4 Preparation in the Swedish Penal Code

Regarding preparation to an infringement the same rule as to attempts should be applied meaning that the rightholder should not need to prove that the preparation has been made by intention or negligence.[80] However, in order for the situation to constitute a preparation

---

[75] Prop. 2008/09:67, p. 287.

[76] 23:1 §, Swedish Penal Code (1962:700).

[77] L. Holmqvist, M.Leijonhufvud, P.O. Träskman, S.Wennberg, Brottsbalken – En kommentar, Del II (13-24 kap.), Brotten mot allmänheten och staten m.m, Studentutgåva 5, Norstedts Juridik AB, p. 23:6.

[78] L. Holmqvist, M.Leijonhufvud, P.O. Träskman, S.Wennberg, Brottsbalken – En kommentar, p. 23:6.

[79] L. Holmqvist, M.Leijonhufvud, P.O. Träskman, S.Wennberg, Brottsbalken – En kommentar, p. 23:6.

[80] 23:2 § Swedish Penal Code (1962:700) and P. Sande – constitutional commentary to the Swedish Patent act, 9:57b § third paragraph, number 211, Karnov, last visited 19th of March 2012.

the conditions set out in 23:2 § in the Swedish Penal Code must be fulfilled. 23:2§ states that:

"A person who, with the intention of committing or promoting a crime, presents or receives money or anything else as pre-payment or payment for the crime or who procures, constructs, gives, receives, keeps, conveys or engages in any other similar activity with poison, explosive, weapon, picklock, falsification tool or other such means, shall, in cases where specific provisions exist for the purpose, be sentenced for preparation of crime unless he is guilty of a completed crime or attempt." [81]

A preparation is characterized of that the person has not yet left the planning stage to commit the crime and the crime plan has not been executed to the degree that it would lead to a complete crime.[82] A preparation is further limited to the two stated actions in the paragraph namely to present or receive any payment in order to execute the crime or to use any tools as a mean in order to commit the crime. Tools in the paragraph relates to criminal use of any tools. However, a lawful use of any tool can also be considered to be a tool to commit a crime in accordance with the paragraph if the tool is particularly suited for the actual crime.[83]

If putting the definition of a preparation in relation to an offering of generic drugs it seems that a preparation to offering generic drugs could exist on an earlier stage in comparison to an attempt to offer the generic drugs. Although the idea with attempt and preparation is that the applicant for the interim injunction does not need to prove any intention or negligence by the other party it is a necessity in order for a preparation to be at hand that the other party has had an intention to commit or promote an offering of the generic drugs.

4.4 Concluding remarks

As stated above the directive did not give any guidelines on how to interpret an imminent IPR infringement. However, Sweden established that such a situation should be interpreted as an attempt or preparation to an IPR infringement. In this sense Sweden is the only country in the EU which has an explicit rule regarding interim injunctions against attempt and preparation to an infringement. This could be seen as somewhat unfortunate since the

[81] 23:2 § Swedish Penal Code (1962:700).

[82] L. Holmqvist, M.Leijonhufvud, P.O. Träskman, S.Wennberg, Brottsbalken – En kommentar, p. 23:24.

[83] L. Holmqvist, M.Leijonhufvud, P.O. Träskman, S.Wennberg, Brottsbalken – En kommentar, p. 23:24.

purpose with the directive was to create uniform rules on enforcing IPRs throughout the member states of the EU.

It is clear that both attempt and preparation are actions that are taken before an actual infringement has occurred. It is also clear that Sweden in its implementation has gone further than other member states when it comes to the possibility to obtain interim injunctions against another party before an actual infringement occurs. In this regard especially a preparation could probably exist a long time before an actual infringement has occurred depending on what kinds of preparations and planning that is made by the other party.

If looking at the definition of an attempt stated in the Swedish Penal Code an attempt should be considered to be at hand when someone has started to commit a crime but the crime has not been completed if there was danger that the act would lead to a completion of the crime. In order for an attempt to exist the person should therefore has left the planning stage and has done everything according to the crime plan in order for the crime to be complete if the situation continues to develop in the way that he has imagined. However, an attempt could also be at hand in cases where there exists something more to be done if the remaining things are in close connection to the thing that has already been done both in the action itself but also in time.

If putting the term offering to the above definition, an attempt to offer should therefore be at hand when the generic company has started to commit an offering but it has not been completed, if there is a danger that the action would lead to a complete offering. Further, an attempt to offer could therefore either be in the case when the generic company has done everything according to the plan in order for the crime to be complete if the situation continues to develop in the way that the generic company has imagined. However, as a second example an attempt could also be at hand when the generic company has something more to do if the remaining things are in close connection in time and in action to the things that has already been done.

When it comes to cases of preparation the Swedish Penal Code states that:

"A person who, with the intention of committing or promoting a crime, presents or receives money or anything else as pre-payment or payment for the crime or who procures, constructs, gives, receives, keeps, conveys or engages in any other similar activity with poison, explosive, weapon, picklock, falsification tool or other such means, shall, in cases

where specific provisions exist for the purpose, be sentenced for preparation of crime unless he is guilty of a completed crime or attempt"

Since the above definition states that a preparation may be at hand if not the person is found guilty of a completed crime or attempt a preparation may therefore probably exist on an earlier stage in comparison to an attempt. Although the idea with interim injunctions is that the applicant does not need to show any intention or negligence by the other party it is a requirement that a preparation is made with an intention to commit or promote a crime. Therefore if putting the term offering in relation to a preparation there is a need that the generic company has an intention to commit an offering of the generic drugs in order for there to be seen as a preparation. Further, the generic company has to in some way engage or use some kinds of tools in order to prepare for the offering of the drugs. It has been established that also lawful use of any tools may be considered to be a tool to commit a crime (offering) if it is particularly suited for the actual crime.

5 Established offering of generic drugs

5.1 Introduction

As been established in chapter 4 (especially 4.3.3) the definition of an attempt is that someone has started to commit an offering but it has not been completed. Further the definition of a preparation is that someone has the intention to commit or promote an offering by using any tools in order to commit the offering. Since the purpose of this thesis is to investigate when interim injunctions may be obtained against an attempt or preparation to offer generic drugs on the market there is a need to investigate what actions taken by generic companies are to be seen as actual offerings of the generic drugs. Questions of what particular actions taken by generic companies during the patent protected period that would be seen as an offer has been highlighted in several Swedish cases. This chapter will therefore examine the current rules stated in the Swedish Patent Act together with relevant case law in order to establish the borderline between actions that falls under the scope of an offer and allowed actions taken by generic companies.

5.2 The court's reasoning

In particular three cases, the Carboplatin, Sertraline and the Merck case the Swedish court have established principles in determining of when actions taken by generic companies during the patent protected period on the original drug is to be seen as an offering of the generic drugs. In the examination of the term offering the court has further briefly discussed if some of the actions that has been considered not to constitute an actual offering at least could be seen as a preparation by the generic company to later offer the generic drugs.

5.2.1 The Carboplatin case

In the case the question was whether an infringement had been made of the indirect product protection of a pharmaceutical process patent. The Research Corporation Technologies Inc. had a patent protection for the process of producing the compound Carboplatin in which they had licensed out the right to the Bristol- Myers Squibb Company to use the patent. The protection on the patent expired in 1993 and in 1994 an SPC on the pharmaceutical was obtained until 1999.[84] The Cyanamid Nordiska Aktiebolag (named Lederle) applied in 1990 to the Swedish Medical Product Agency (MPA) of registration of their generic preparation Carboplatin Lederle and at the same time submitted two small bottles con-

[84] T 7-536-93/T 7-737-94, p. 2.

taining the active substance which they had brought in to the country. In 1992 Carboplatin Lederle was registered as a pharmaceutical. At this time Lederle also left information regarding the product to the Swedish Läkemedelsinformation AB and because of that became included into the FASS (pharmaceutical Specialties in Sweden) registry. At this point Lederle also presented a document to the university hospital in Linköping named "proposal to an agreement" in which certain discounts of a certain purchase volume were presented to the hospital.[85] Bristol- Meyers claimed that such actions taken by Lederle constituted an infringement on their patent protected Carboplatin.

The District Court highlighted two different questions. First whether a generic substance which has been produced according to a patent protected process is allowed to be brought in to the country and submitted to the MPA. Second if some written documents should be seen as an offering of the substance.[86]

The District Court especially pointed out that the submitting of the two bottles of the active substance was to be seen as a part of a planning after the protection on the pharmaceutical had expired commercially to put the pharmaceutical on the market. The District Court held that the exclusive right of a patent also included actions that were taken in a forward- looking purpose and therefore the submitting of the bottles to the MPA was to be seen as a patent infringement. On the same grounds the court held that the importation of the substance also should be seen as an infringement. However, the court further stated that the mere request for a market approval to the MPA and the submitting of information to the same would not constitute an offering. In other words the purely administrative paper work which is required to be handled in to the MPA in order to get a market approval did not constitute an infringement. The critical point for a patent infringement in the actual case was therefore the submitting to the MPA of the two bottles containing the active substance.[87]

The court further stated that information regarding pharmaceuticals will be included only into the FASS registry if the company is taking actions in order to get the information included. To publish the information in the FASS registry should therefore be seen as a method in order to sell the pharmaceutical and therefore constituting an offering. Further,

[85] T 7-536-93/T 7-737-94, p. 2.

[86] T 7-536-93/T 7-737-94, p. 4-5.

[87] T 7-536-93/T 7-737-94, p. 4.

regarding the "draft agreement" which Lederle submitted to the university hospital the court held that such contacts stating certain discounts on the amount of purchase volumes was without a doubt an offering in accordance with the Swedish Patent Act. The situation that Lederle in the "draft agreement" informed the hospital that the pharmaceutical was only available for selling after the protection had expired did not change the fact that it still was an offering of the pharmaceutical.[88]

5.2.2 The Sertraline case

The ruling in the case was decided in 2008 and therefore one year prior to the implementation of the attempt and preparation rule regarding interim injunctions in the Swedish Patent Act.[89]

The dispute in the case was between the pharmaceutical giant Pfizer AB (Pfizer) and STADApharm AB (STADA). Pfizer was the holder of a SPC on the pharmaceutical product Sertraline which is a medicine to combat depression. The product was protected through a basic patent which had been extended through the SPC. The basic patent had expired in year 2000 and the SPC was extended to 28 of Oct 2005. In Dec 2004 the Swedish Medical Products Agency (MPA) decided that the generic product Sertraline STADA manufactured by the generic drug company STADA was allowed to be sold in Sweden. In April 2005 six months before the expiration STADA applied to the Swedish Dental and Pharmaceutical benefits Agency (TLV) requesting that the generic product Sertraline STADA would be a part of the Swedish pharmaceutical benefits scheme. The product was approved in May 25 2005 and a price for the product was established by the TLV. In the case there was no doubt that the generic product was falling under Pfizer's SPC protection on their Sertraline product. It was however also clear that no selling of the generic product had taken place during the time when Pfizer had an SPC protection on the product. Because of the above stated reasons Pfizer AB sued STADA on the grounds of patent infringement of their protected pharmaceutical product. The question for the District court was whether the actions taken by STADA in the application and the request/discussions for a price setting in which the drugs should be sold to the Swedish pharmacy and sold by

[88] T 7-536-93/T 7-737-94, p. 4.

[89] Before the implementation of the rule regarding injunctions against attempt or preparation to a patent infringement the old rules regarding injunctions was stated in 9:57a § in the Swedish Patent Act.

the pharmacy of the generic drug agency was to be seen as an offering of the generic drugs and therefore constituted an infringement of the protected product.

The District court stated that when it comes to establishing whether an offering has been made or not it is of importance to look at the public laws relating to the marketing of pharmaceuticals on the Swedish market. The court stated that if a pharmaceutical company wants to market a drug on the Swedish market they have to apply and receive a market approval from the MPA and that such application, regarding paper handling issues, is not to be seen as an offering of the generic drug.[90] However, the court highlighted the fact that there is no common definition in Swedish or international law of what constitutes an offering and therefore it is does not matter how the offering has been made, only that there has been an offering. The offering does not need to include a selling of the generic drug; it is enough that it includes any expression of a desire to under commercial conditions provide a product.[91] The term offering should therefore be given a wide interpretation and it does not matter whether a selling of the product or delivery is being made after the protection has expired.[92] Further, the court stated that the difference between an application for a market approval (which do not constitute an offering) and an application to be a part of the TLV is that in the first case it is an absolute necessity to have a market approval in order to even have a possibility to sell the products in the future which is not the case regarding the pharmaceutical benefits scheme. In the latter case it is up to company that is marketing the drug themselves to decide. On the above mentioned grounds the court of first instant therefore argued that an application to the TLV was to be seen as an offering of the product and therefore constituted a pharmaceutical patent infringement.[93]

The Court of appeal however had a different opinion in the matter. Although the court agreed with the District court that there has to be an expression of a desire to under commercial conditions provide a product. Since there is no common definition of the term offering it is not important how the product has been offered, it could be through writing, orally, via advertising, by phone or demonstration etcetera.[94] The Court of appeal highlight-

[90] NJA 2008:110 p. 1196.

[91] NJA 2008:110. p. 1198.

[92] NJA 2008:110. p. 1198.

[93] NJA 2008:110. p. 1199.

[94] NJA 2008:110. p.1202.

ed the fact that in order for it to be seen as an offering it has to be related to a proposed transaction. If STADA, during the time of the application to the TLV, would have turned directly to a potential customer and provided the product for selling after the patent protection had expired that would constitute an offering according to the Swedish Patent Act. In this case the application was made only to a government agency which is not a potential customer of the product since there is no desire to get the authority to acquire the product.[95] The TLV is also not to be seen as a representative or negotiator for a potential customer, in this case the Swedish pharmacy, but merely an independent authority. Thus, the application of a price setting was not addressed to a potential customer and was not connected to some sort of business transaction and therefore did not constitute an offering of the generic drugs. However, the Court of appeal stated that such application to the TLV was merely to be seen as a preparation to in the future offer the generic drugs.[96]

The case was appealed to Supreme Court which overall followed the reasoning from the Court of appeal. The Supreme Court stated that the TLV´s task is to be responsible for subsidy and price setting of drugs that is a part of the pharmaceutical benefits scheme. An application to the TLV is therefore addressed to a government authority which is not aiming at acquiring the product for themselves or someone else. On those grounds the actions taken by STADA could not be seen as an offering of the generic drugs and therefore the situation did not constitute a patent infringement.[97]

5.2.3 The Merck case[98]

The Merck case was decided in June 2010. It was a complicated case extending over a long period of time with many different pharmaceutical companies involved. On one side there was the MSD Overseas Manufacturing Co. and Merck Sharp and Dohme, hereinafter Merck companies and on the other side Teva Sweden, Arrow pharmaceuticals and Arrow generics. The case handled several questions not related to patent infringements and which will not be highlighted below. It was also established in the case that Teva Sweden and Arrow pharmaceutical did sell its generic drugs in the Swedish pharmacies under year 2005

[95] NJA 2008:110. p. 1203.

[96] NJA 2008:110.p. 1204.

[97] NJA 2008:110.p 1207.

[98] Joined cases, T 16665-04, T 252-05, T 15175-05, T 7337-05, T 15141-05, T 30912-05, T13939-05.

while the Merck companies had a protected patent.[99] The mentioned situation is not relevant to discuss below since the selling of the generic drugs in 2005 was without a doubt a patent infringement of Merck's patent protected pharmaceutical.

However, the District Court made an examination whether other actions taken by the companies constituted an offering of the generic drugs which is of importance for this thesis. In the case the District Court also discussed the new rule regarding injunctions against attempt and preparation to an infringement which is of highly importance for the purpose of this thesis.

The three major situations of claimed offering that the District Court examined were

1. Whether actions taken by Teva with its generic drug ALENDRONAT TEVA and Arrow Pharmaceuticals with its generic drug ALENAT constituted an offering of the pharmaceuticals and therefore constituted a patent infringement of the patent protected FOSAMAX held by the Merck companies. The Merck companies had an SPC protection on the drug FOSAMAX until April 2008. In November 2004 the generic drug ALENDRONAT TEVA was approved by the Swedish MPA to be sold in Sweden.[100] During this time the company went out in the daily news letter Pharma Online and declared that the drug will be sold within the near future. At this point it was still over three years left until the SPC protection on the Merck companies FOSAMAX was expired.[101] The Merck companies claimed that this action was to be seen as an offering of the generic drug.

2. Teva Sweden also applied to the TLV that their generic drug ALENDRONAT TEVA would be a part of the pharmaceutical benefits scheme and that a price for the drug would be established. The decision on the price of the drug was established in November 2004 and the selling price for the generic drug was 30% lower than the price for the protected FOSAMAX.[102] Since Teva Sweden started to sell the generic drug after the application to the TLV the Merck companies claimed that

[99] T16665-04 multi, p.184

[100] T16665-04 multi, p 154.

[101] T16665-04 multi, p 154.

[102] T16665-04 multi, p 154.

such actions as well are to be seen as an offering or at least a preparatory measure to infringe the protected patent.[103]

3. As a third the Merck companies claimed that the presence of product information on the generic drugs in the FASS database and on the Swedish pharmacies website constituted an offering of the generic drugs.[104] The FASS database contains information of approved pharmaceuticals that is marketed on the Swedish market.

The District Court followed in its examination previous statements regarding offering in the area. First of all they declared that the exclusive right should also cover such offering of products which is made during the protected time but is relating to delivery first after the protected time.[105] The court further referred to the judgment in the Sertraline case (discussed above) that an offering includes any expression of a desire to under commercial conditions provide a product. In the case Teva Sweden`s statement in the newsletter Pharma Online had such a meaning that it gave potential customers a reason to believe that Teva Sweden would introduce its product in the future and that such statements, directed against potential customers, was to be seen as a desire to under commercial conditions provide a product.[106]

The court further stated that the fact that product information of the generic drugs was in the FASS database and the Swedish Pharmacies website did not constitute an offering of the generic drugs since Teva Sweden and the other companies could not be responsible for information that third party choose to put out on their websites. However, the court further stated that the situations of offering could be interpreted differently if there was evidence that the generic companies in some way had urged that the information would be put out on the database and the website. This however was not the case in the mentioned situation.[107]

Regarding Teva Swedens application to the TLV the court stated, in reference to the Sertraline case, that such application is never to be seen as an offering of the generic product

[103] T16665-04 multi, p. 185.

[104] T16665-04 multi, p.186.

[105] T16665-04 multi, p.186.

[106] T16665-04 multi, p.186.

[107] T16665-04 multi, p.186.

since the purpose of the application is not to get the authority to acquire any right to the product. This statement follows previous statements in the area but it also does not matter whether an actual selling of the product is followed after the application to the TLV.[108] The Merck companies however claimed that such an application at least should be seen as a preparatory measure to an infringement. The District Court highlighted the fact that when an application to the TLV was examined in the Sertraline case there was no possibility for companies to protect themselves against attempt or preparation to infringements. The District Court further stated that today in accordance with the new rules followed from the implementation of the Enforcement Directive there could be a possibility that the application to the TLV constituted a preparation to an infringement. The court however declared that it was already established that Teva Sweden had completed an infringement by both offering and selling the product and that there was no need to also do an examination on whether the application constituted a preparation to the already completed infringement.[109]

5.2.4 What would constitute an offering of generic drugs?

In the three mentioned cases many different actions taken by a generic company were examined. As stated above the term offering is not defined in the Swedish Patent Act and therefore Swedish case law is important in order to get some guidance in what direction the concept is going. However, since the cases are dealing with particular actions taken by a generic company in particular situations the case law only takes small steps forward every time in the clarification of the term offering.

Principles established in the cases:

- The exclusive right should include actions that are taken in a forward-looking purpose.
- Offering should be given a wide interpretation.
- An offering does not include a selling of the generic drugs; it is enough that it includes any expression of a desire to under commercial conditions provide a product.
- The offering has to be related to some form of proposed transaction.

[108] T16665-04 multi, p. 185.

[109] T16665-04 multi, p.186.

- Offering of products which is made during the protected time but is relating to delivery first after the protected time is still to be seen as an offering.
- It is not important how the offering has been made, it could be through writing, orally, via advertising, by phone or demonstration etc.

Allowed actions established in the cases:

- Administrative measures (paper handling issues) in order to get a market approval of the generic drug. This is a general view in all member states of the EU.

- An application to the TLV and discussions regarding the sales prices is not to be seen as an offering of the generic drugs since the contact is not aimed at a potential customer but merely a government authority which is not aiming at acquiring the product for them or someone else. The action is therefore not connected to some form of a business transaction.

Prohibited actions established in the cases:

- The submission of physical samples of the pharmaceuticals to the MPA which has been manufactured through a patent protected process. It is therefore allowed to submit "paper work" but not submit samples of the drug.

- To publish information regarding the generic drug on websites and databases if it is a deliberate action taken by the company. In the Carboplatin case it was shown to be a deliberate action. In the Merck case there was not enough evidence that showed that the company had urged that the information would be published on the pharmacies website and the FASS database. According to the Merck case if there is no such evidence a generic company cannot be responsible of what a third party chose to publish on their websites.

- Statements in newsletters that the generic drugs will be available in the future which gives potential customers the reason to believe that they soon can buy the generic drugs.

- The establishment of a draft agreement with a potential customer before the patent protection had expired. It does not matter whether the generic company informed

the potential customer that a selling was possible only after the protection had expired.

5.2.5 The brief discussion on preparation to offer

Although the question in the cases was whether actions taken by the generic company was to be seen as patent infringement the court also had a brief discussion regarding preparation to pharmaceutical patent infringements in the Sertraline and Merck case. In the Sertraline case it was established that an application for a price setting to the TLV did not constitute a patent infringement since the application was not addressed to a potential customer and was also not connected to some sort of business transaction. In a very brief discussion Court of appeal declared that an application to the TLV may instead be seen as a preparation by the generic company to in the future offer the generic drugs. How that statement should be interpreted today is very unclear since the Court of appeal did not give any further guidance as to why such an application may constitute a preparation by the generic company. In the Merck case the court also held that there was a possibility that an application to the TLV could constitute a preparation and made a reference to the Court of appeals reasoning in the Sertraline case. Unfortunately the court did not further examine whether that was actually the case since it was already established that the generic company had made a complete infringement on other grounds by offering and selling the generic drug.

5.3 Exceptions to patent infringement

Although the idea of a patent protection is to give the patent holder an exclusive right to commercially exploit the invention there are five exceptions to the exclusive right stated in the Swedish Patent Act.

1. Use which is not commercial
2. Use of a product protected by the patent which is put on the market within the European Economic area by the proprietor of the patent or with his consent
3. Use of the invention for experiments which relate to the invention itself
4. Studies, trials, surveys and practical measures which is referring to a reference drug (original drug), to the extent that such measures is necessary in order to get a market approval in the implementation of 8a§ of the Swedish Medical Product Act (1992:859)

5. Preparation in a pharmacy of a medicine in accordance with a physician`s prescription in individual cases or acts with the medicine so prepared.[110]

The relevant exceptions for this thesis and which will be examined below is the experimental exception in point 3 and the exception for studies, trials and surveys in point 4.

5.3.1 Experimental use

It is a commonly universal rule that experiments on patented inventions is allowed since the purpose with the patent system is to promote technical development and it would be counterproductive not to allow experiments.[111] The experimental exception means that it is allowed to conduct experiments on a patent protected product without a need to have an approval from the patent holder. The exception therefore decides the border between what studies that can be made by a generic company on the original drug under the patent protected period. The experimental use clause was implemented into the most European countries during the 1970s and in the Swedish Patent Act in 1978. The main reason for such a clause was that it should make it easier to research on and further develop existing patent protected inventions.[112]

The interpretation of what actions taken by a generic company should fall under the scope of the experiment exception differs widely between the member states of the EU. According to Swedish law however a patented invention should be the "object" for the experiment in order to fall under the scope of the exception. In other words it is the patented product which has to be of interest for the studies.[113] A company cannot rely on the experiment exception merely because the patented product is a part of another research.[114]

5.3.2 Clinical studies for generic pharmaceuticals

There is a high interest for generic companies to be able to conduct as much tests and experiments as possible during the time there is a patent protection on the pharmaceutical.[115]

---

[110] 1:3 § third paragraph point 3, Swedish Patent Act (1967:837).

[111] B. Domeij, Läkemedelspatent, p. 457.

[112] SOU 2008:20, p. 360.

[113] SOU 2008:20, p.369.

[114] SOU 2008:20, p.369.

[115] B. Domeij, Läkemedelspatent, p. 457.

The competitive situation between generic companies is high and it is important to be first on the market with a cheaper generic drug once the patent protection has expired.[116]

In 2006 Sweden implemented a new exception to the exclusive right stated in the patent act. The exception is applicable when it comes to studies, trials, surveys and practical measures which is referring to a reference drug (hereinafter original drug) in order to get a market approval in the implementation of 8a§ of the Swedish Medical Product Act (1992:859).

The implementation of the new exception is based on the directive 2004/27 EC[117] which was a changing directive to the 2001/83 EC. The idea with the directive was to facilitate the free movement of human drugs on the European market. The idea was also to make it easier for generic pharmaceuticals to access the European market.[118]

In order for a generic drug to be allowed to be sold in Sweden it will need a market approval. As stated in the Carboplatin case (5.2.1) the paper work needed to get an approval did not constitute an infringement, however the submission of physical samples of the generic drug was a prohibited action. Before the implementation of the new exception there was a need, in most European countries, to submit physical samples of the generic drug in order to get the approval.

In the Swedish Medical Product Act it states that when a market approval has been granted for a pharmaceutical any additional strengths, pharmaceutical forms, packaging forms, as well as any variations and extensions shall be included in the original market approval.[119] This shall also be the case in the implementation of 8a§ in the Swedish Medical Product Act and shall be considered to belong to the same approval.[120]

8a§ in the Medical Product Act states that a generic company in their application for a market approval do not need to submit results of any preclinical or clinical studies of the generic drug if they show that the drug is a generic to a original drug which is or have been

[116] B. Domeij, Läkemedelspatent, p. 457.

[117] Directive 2004/27 EC of the European Parliament and of the Council of 31 march 2004 amending directive 2001/83 EC on the Community code relating to medicinal products for human use.

[118] Prop. 2005/06:70, p. 2.

[119] 8d §, Swedish Medical Product Act (1992:859).

[120] 8d §, Swedish Medical Product Act (1992:859).

approved in a state within the European economic area for at least the last eight years.[121] The rule states that a company that is applying for a market approval for its generic drug can provide documents of the preclinical and clinical studies that the company holding the patent on the original drug made in their application for a market approval. Instead of carrying out new preclinical and clinical test for the generic drug a company can therefore submit the documents referring to the studies of the original drug.[122] The documentation resources needed in order to get a market approval for the generic drug is therefore set out lower than before and the market approval can be obtained much faster than before.[123]

The background to the directive 2004/27 EC was to facilitate the entering of generic drugs on the European market. The new rule therefore makes it easier for generic companies to obtain a market approval for their generic drugs since there is no longer a requirement to submit physical samples of the drug in the application for a market approval. As stated in the Carboplatin case a submission of physical samples was an action taken by a generic company which constituted a patent infringement. Because of that generic companies had to wait to submit the samples to after the patent protection on the original drug had expired.[124] A company could therefore not obtain a market approval during the time there was a patent protection on the original drug. The result was that it took a longer time after the protection had expired to launch the generic drug on the market. An effect of the new exception is that a company can manufacture and obtain a market approval during the time there is a protection on the original drug and directly after the protection have expired start to sell the generic drug on the market.

5.4 Concluding remarks

Through the above mentioned cases the Swedish court has somewhat clarified the term offering set out in the Swedish Patent Act. It has been established than an offering should include any expression of a desire to under commercial conditions provide a product. Further the offering has to be related to some form of proposed transaction. On those grounds the court has given the term offering a very wide definition and many actions taken by a generic company could probably be seen as an offering of the generic drugs.

---

[121] 8a §, Swedish Medical Product Act (1992:859).

[122] 8a § point 1-2, Swedish Medical Product Act (1992:859).

[123] Prop. 2005/06:70, p. 95.

[124] B. Domeij, Läkemedelspatent, p. 459.

It has been established that an offering of the generic drugs could be made in several different ways, for example through written letters, oral, by phone through advertising and demonstration etc. It therefore seems that the important thing in establishing an offer is not how the generic drugs have been offered but to whom it has been offered.

Since it has to be a desire for the generic company to under commercial conditions provide the product and further has to relate to some form of a business transaction the offer probably needs to be made with the purpose for the generic company to in the future sell the products. On those grounds the party that receives the offer as well would probably need to have an interest or be capable to in the future buy the products. An application and discussions regarding the price setting of the generic drugs to the TLV was therefore not to be seen as an offering of the generic drugs. That was the case since there was no desire to get the authority to acquire the products and hence the TLV was therefore not any potential customers to the products.

Further it has been established that an offering is still to be seen as offering even if the generic products are meant to be delivered first after the patent protection on the original drug has expired.

Although it has been established that merely contacts with different authorities such as the application and obtaining of market approval and applications and discussions regarding price settings on the generic drugs do not constitute an offering since they have not been made to potential customers some discussions has been held whether applications to the TLV would constitute a preparation to offer the generic drugs. In this regard the court especially in the Merck case held that such actions may very well be seen as a preparation in order to offer the generic drugs. However unfortunately the court did not investigate further whether the actions actually constituted a preparation or not.

6 Danish case law on an imminent situation

6.1 Why Denmark?

When it comes to the establishment of an attempt or preparation to offer generic drugs no Swedish case law is available and Swedish legislation do not provide anything more than general principles on how attempt and preparation would be established in accordance with the rules set out in the Swedish Penal Code. Although Sweden is the only country in Europe to have an attempt or preparation rule Denmark has established principles in Danish case law of when interim injunctions may be issued against a generic company in the situation of an imminent pharmaceutical patent infringement. In this regard an examination of the court's reasoning on how to establish an imminent pharmaceutical patent infringement will therefore be made. The particular reason for using Denmark is since Denmark and Sweden has to a large extent uniform Patent Acts due to the Nordic patent reform which was established in the 1960s. In the analysis references will therefore be made to the principles regarding an imminent pharmaceutical patent infringement in Danish case law in order examine whether some guidance on how to interpret an attempt or preparation to offer generic drugs in accordance with the Swedish Penal Code could be made. The reader should however bear in mind that since Denmark and Sweden does not have equal rules regarding the possibility to issue interim injunctions a restrictive interpretation of the findings in the Danish case law must be made.

6.2 Interim injunction in Denmark

The possibility to apply for interim injunctions in Denmark is a process based on the provisions stated in the "retsplejeloven".

In article 641 it is stated that

"the court can apply a prohibition against individuals and representatives for a state, region or municipality in their capacity of parties in private legal matters to refraining from actions which is contrary to the applicant`s right"

In comparison to the Swedish legal system (see 2.2) in which interim injunctions can be granted either through the intellectual property laws or the Swedish Process Act it is only a possibility to apply for interim injunctions in the Danish legal system through the provisions set out in the Danish Process Act "retsplejeloven".

The conditions for granting an interim injunction according to the law is that first of all (1) the actions which the prohibition is applied for is contrary to the applicant`s right, (2) the counterparty will undertake the actions for which the prohibition is applied for and (3) the subject for the application will be lost if the applicant is directed to claim his right at an ordinary court. Further, the applicant must show or demonstrate probably cause to believe that the conditions stated above exists. [125]

It is also stated in the law a proportionality test meaning that the Danish court can refuse to issue an interim injunction if it would cause damage or detriment to the counterparty and that it is in obvious disproportion to the applicant`s interests that an injunction is being granted.[126]

In order for a pharmaceutical company holding a patent to issue an interim injunction against a generic company they therefore have to show that the actions for which they have applied an interim injunction is in some way contrary to their rights given by the patent. The interim injunction is therefore aimed at prohibiting the generic company to infringe the patent. They also have to show that the generic company will undertake the actions for which the interim injunction is issued, in other words undertake actions that will constitute a pharmaceutical patent.

6.3 Case law

In especially two cases in Denmark the court has issued interim injunctions against another company when there has been a high risk for a future pharmaceutical patent infringement and that the situation therefore has constituted an imminent situation. In the examination of whether the situation has constituted an imminent pharmaceutical patent infringement the Danish court has especially looked at whether the company holding the patent has shown enough evidence or probability that a pharmaceutical patent infringement will occur in the future.

6.3.1 Novartis vs. Teva

The case was between Novartis AG and Novartis Healthcare (Novartis) and Teva Denmark A/S (Teva) in which Novartis was the holder of a patent on the drug Valsartan.

[125] 642 § point 1-3, Retsplejeloven.

[126] 643 § paragraph 2, Retsplejeloven.

In the case Novartis in September 2007 applied to Lyngby Fogedret an interim injunction against the generic pharmaceutical company Teva. In 2006 Teva had applied to the Danish "Laegemiddelstyrelsen" (The Danish equivalent to the Swedish Medical Product Agency) and asked for a market approval of their generic drug containing the active ingredient Valsartan despite that Novartis had an SPC on the original drug until 2011. Because of this Novartis contacted Teva and demanded that Teva would declare that they would not start any marketing of the generic drug until the SPC protection on the original drug had expired.[127] Novartis also requested Teva to provide a guarantee that the legality of the marketing of the generic drug would be tested in a court before Teva started to market the generic drug. Teva in the case responded that they would not declare such a thing but announced that they did not have any plans to market their generic drug in Denmark. Further, Teva stated that the primary reason for the market approval was to use Denmark as a reference state in a procedure for a decentralized market approval and that Teva at the moment did not consider the patent to be invalid and that they realized that they at the moment could not legally market the generic drug on the Danish market.[128]

The Lyngby Fogedret started to declare that the general opinion regarding the applications for market approval of generic drugs was that only the application for market approval was not enough to issue interim injunctions against a generic pharmaceutical company. This statement is in line with the general view in all member states of the EU.[129] Lyngby Fogedret looked in its examination on the criteria for issuing interim injunctions stated in the "retsplejeloven" and particular highlighted the fact that the company which is applying for the interim injunction need to show sufficient degrees of evidence that the generic company will undertake the actions for which the injunction is applied for. The company should therefore have to show sufficient degrees of evidence that the Teva will make, offer, bring to market or use the generic product during the patent protected time.[130] Lyngby Fogedret found that the statements made by Teva in which they announced that they did

[127] Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008, p.1.

[128] Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008, p. 3.

[129] Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008, p. 3.

[130] Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008, p.4

not have any plans to market the generic drug and that the approval only was to be seen as a process in order to get a decentralized approval were declarations that showed that no marketing in the near future would take place. Lyngby Fogedret pointed out that Teva had not taken any concrete measures in order to start marketing the generic drug. Because of this and the above stated declarations from Teva Lyngby Fogedret found that Novartis had not shown sufficient degrees of evidence that Teva would in the future infringe the patent.[131]

The case was appealed to the Östre landsrett which followed much of the reasoning stated by Lyngby Fogedret but although had a different view in the matter. The Östre landsrett also highlighted the fact that only the application for a market approval was not to be seen as a patent infringement. The court however stated that an application together with other surrounding circumstances could show the possibility that the company in the future would infringe the patent and that such signs could be enough reasons to issue interlocutory injunctions before an actual infringement has occurred. The Östre landsrett highlighted the fact that Teva on a very early stage in comparison to when the protection on the drug expired applied for a market approval for the generic drug.[132] The östre landsrett further highlighted that since Teva did not wish to declare that they wanted to respect Novartis patent rights it was a possibility that Teva would take actions that could infringe Novartis patent in the future. Teva`s argument that the application was made only in the procedure to use Denmark as a reference country in the decentralized procedure did not change the fact that a patent infringement of Novartis protected drug was imminent. Östre landsrett therefore issued an interim injunction against Teva on the grounds of an imminent pharmaceutical patent infringement.[133]

6.3.2 Eli Lilly Denmark vs. Nomeco

In the second case the pharmaceutical company Eli Lilly applied for an interim injunction against Nomeco (One of three full-range wholesaler of pharmaceuticals in Denmark are

[131] Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008, p.4.

[132] Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008, p.7.

[133] Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008, p.7.

obligated to provide all pharmaceuticals brought up in the Danish Medicinregisteret).[134] The reason for the application was that Eli Lilly in 2007 noticed that several generic companies had applied and obtained market approvals for their generic drugs although that Eli Lillys patent on their drug did not expire until 2011. Eli Lilly contacted the generic companies in question and wanted them to confirm that they would not market their generic drugs until the patent protection on Eli Lillys drug had expired. The generic companies responded that they did not have any plans to market their generic drugs in Denmark but their answers indicated that they did not believe that their generic drugs was infringing the patent or regarded the patent to be invalid. In addition it was also established that the generic drugs already had been put on the English market with a patent infringement as a result and Eli Lilly therefore claimed that there was a concrete risk that the generic companies would use their obtained market approvals in order to start marketing the drugs on the Danish market.[135]

According to Danish law a full-range wholesaler has to sell all products brought up in the "Medicinregisteret".[136] If the generic companies would sign up their products in the "Medicinregisteret" Nomeco therefore had to sell the generic drugs regardless if the patent holder claims that such actions constitutes a patent infringement. Eli Lilly therefore applied for an interim injunction against Nomeco in order not to promote the infringing generic drugs.

The Frederiksbergs Fogedret started to declare the already established rule that an application and granting of a market approval are not to be seen as a patent infringement. The court however declared that such actions taken by generic companies is a central act before a marketing of the drug could begin and that such actions creates a natural presumption that the company has the intention to sell the product, which was the case in England and which had constituted a patent infringement. The court further stated that although the generic companies had declared that no marketing of the drugs would take place during the patent protected time no one of the companies had explained as to why they had applied

[134] Before the abolition of the monopoly of pharmacies in Sweden in 2009 Apoteket would probably be the nearest equivalent to Nomeco.

[135] Eli Lilly and Company Ltd. And Eli Lilly Danmark A/S vs. Nomeco A/S, Retten på Frederiksberg, FS 1-13061/2007, 28th of April 2008. See also P. U. Plesner, C.Thufason – Udviklingen af immaterialretten I Danmark, NIR 2008, p. 528-529.

[136] P. U. Plesner, C.Thufason – Udviklingen af immaterialretten I Danmark, NIR 2008, p. 528.

for the market approvals. Further the court held that Nomeco had not declared that they would not market the generic drugs and there was therefore a presumption that Nomeco would provide the generic products if the generic companies would apply to the "medicinregisteret". On those grounds the court held that Eli Lilly had shown sufficient degrees of evidence that a marketing of the generic drugs would take place during their patent protected time.[137]

6.4 Concluding remarks

Although Denmark does not have any rule regarding interim injunctions against attempt or preparation to a patent infringement the two above mentioned cases state that interim injunctions could be issued in Denmark on the grounds of an imminent patent infringement and therefore before an actual infringement of the pharmaceutical patent has occurred. The Danish court has in its examination in particular looked if the actions taken by the generic companies showed enough signs or evidence that they in the future would commit any of the prohibited actions stated in the Danish Patent Act. In both Novartis vs. Teva and Eli Lilly vs. Nomeco the generic companies had obtained market approvals for their generic drugs but as stated only the market approval do not constitute a patent infringement. Although the application and obtaining of a market approval is an allowed action the Danish court held that such an approval together with other surrounding circumstances could show signs that the generic company in the future would infringe the patent. What actions that could show such signs are probably depending on the particular situation. However the Danish court held that a generic company's refusal to declare that they would not in the future infringe the patent could be enough reasons to believe that they would take prohibited actions with its generic drug before the patent protection on the pharmaceutical has expired. Further, the court held that if a generic company has applied and obtained a market approval in a very early stage in comparison to when the patent protection expired (for example several years before the expiration) that could also indicate that the generic company was planning to market the generic drug during the patent protected time. The court held that if many generic companies are applying and obtaining market approvals at the same time for their generic drugs there could be a concrete risk that a patent infringement in the future would occur.

[137]Eli Lilly and Company Ltd. And Eli Lilly Danmark A/S vs. Nomeco A/S, Retten på Frederiksberg, FS 1-13061/2007, 28th of April 2008. See also P. U. Plesner, C.Thufason – Udviklingen af immaterialretten I Danmark, NIR 2008, p. 529.

Also in the examination by the Danish court of when an interim injunction can be issued against a generic company on the basis of an imminent pharmaceutical patent infringement the generic company's intention seems to play an important role. What intentions with the applications to the authorities does the generic company have? Is it made only with the purpose to make the marketing of the generic drugs faster after the patent protection expires or is it a deliberate action taken by the company in order to start marketing the drug before the patent protection on the original drug expires?

7 Discussion

7.1 Introduction

In order for a pharmaceutical company holding a patent to be able to issue an interim injunction against a generic company on the grounds of an attempt or preparation to offer the generic drugs the pharmaceutical company has to show a probability that such an attempt or preparation is at hand. In this case the applicant do not need to show according to the rules any intention or negligence by the infringer. However, when it comes to establishing a preparation there has to be an intention by the other party to commit or promote a crime (offering). In order to establish whether an attempt or preparation to offer generic drugs is at hand an examination of the particular situation in accordance with the Swedish Penal Code has to be made. It is clear that both attempt and preparation is something that is done by another party before an actual offering of the generic drugs has occurred. It is further clear that in order for the question of attempt or preparation to offer generic drugs would rise in the first place there has to be a valid patent protection on the original pharmaceutical through either an original protection or an SPC. Further, of course, there has to be a generic drug which is the target for the infringement. The following questions after that is however what kinds of actions that are taken by a generic company would constitute either an attempt to offer a generic drug or a preparation to do the same. If looking at attempt and preparation it is clear that they constitute different kinds of actions that could be taken by a generic company. In the further analysis in this chapter they are therefore examined independently from each other.

7.2 Attempt stated in the Swedish Penal Code in relation to an established offering in case law

The Swedish Penal Code states that a person who has begun to commit a crime without bringing it to completion shall be sentenced for attempt to commit a crime if there was a danger that the act would lead to the completion of the crime. In this regard an attempt should exist when the person has done everything according to the crime plan in order for the crime to be completed if the situation continues to develop in the way that he has imagined (complete attempt). An attempt could however also be at hand if it remains something more to be done if the remaining thing is in close connection to the thing that has already been done both when it comes to the action in itself but also in time(see 4.3.3).

If the above mentioned definition is put in relation to an offering of generic drugs an attempt to offer would in my opinion be understood as the generic company has begun to commit the offering but the offering has not come to a completion if there was a danger that the act would lead to a completion of the offering. If we further put the above mentioned definition to the offering of generic drugs an attempt to offer could in my point of view exist in two ways. An attempt to offer could first of all exist in cases where the generic company has made everything according to the plan in order for the offering to be completed if the situation continues to develop in the way the generic company has imagined. And second of all an attempt to offer could also be at hand when there exist something more for the generic company to do but it is in close connection to the things that has already been done, both the action in itself but also in time (see 4.3.3). In my opinion it is therefore essential to know what constitutes an actual offering in accordance with the Swedish Patent Act in order to establish an attempt to offer the generic drugs.

In the examination of what constitute an actual offering (see chapter 5) the Swedish court determined that an offering should be given a very wide interpretation and should include any desire to under commercial conditions provide a product. In order for it to be seen as an offering the court has declared that the offer has to be related to some form of a proposed business transaction. In my opinion it therefore seems that the generic company must have an intention with the offer to in some kind provide the generic drugs to a party that in their turn have a desire or at least be able to acquire the generic products. In my opinion the party that receives the offer therefore has to in some way constitute a potential customer or buyer of the generic drugs. Further, the Swedish court has established that it does not matter how the generic drugs have been offered. In other words an offering of the generic drugs can be made in several different ways such as through written letters, oral, through demonstrations and advertisements etc. The important thing is therefore not how the generic drugs have been offered but to whom it has been offered. In my opinion in order for an attempt to offer generic drugs would exist the generic company therefore has to start to commit something that in the end would fulfill the above mentioned criterions.

On the above mentioned grounds an example of an actual offer could therefore exist when a generic company has written a paper in which they declare that they want to sell the generic drugs and the letter has been received by a pharmacy. In my opinion the generic company has through the letter first of all showed a desire to under commercial conditions

provide the generic drugs and further includes a future proposed transaction in the sense that the offering has been made in order for the pharmacy to require the products. Further, since it is a pharmacy that is receiving the letter they could be seen as potential customers to the generic company.

In relation to the above mentioned example an attempt is probably deemed to exist before the potential customers have received the information in the letter since as soon they have received the information it will constitute an actual offering. An attempt would therefore in my opinion probably exist somewhere in the timeline between the generic companies establishment of the written letter and the pharmacy's receiving of that particular letter.

An example of an attempt to commit a crime was shown in chapter 4 (4.3.3.). In this example an attempt was at hand when a person had prepared a false tax return and posted it to the tax authorities. In this regard it was considered to be a complete attempt to commit a crime since the person had made everything according to the crime plan in order for the crime to be complete if the situation continued to develop in the way that he has imagined.

On the above grounds if you equate the "crime" with an offering instead a complete attempt to offer the generic drugs could in my point of view therefore exist in the timeline when a generic company has established a written letter (the offer) and further posted it but the pharmacy has not received it yet. In this situation the generic company has made everything according to the plan to offer the generic drugs and as soon the pharmacy has received the letter it will constitute an actual offering. However, as soon as the pharmacy has not received the letter yet it will constitute an attempt.

In order for an attempt to be at hand it could however also remain something more to be done if the remaining thing is in close connection to the thing that has already been done, both in the actions in itself but also in time (see 4.3.3). The question is what could be considered to be in a close connection to the things that has already been done in relation to the above mentioned example. In my point of view since an attempt exists somewhere between the establishment of the written letter and the pharmacy's receiving of the letter such a situation could probably exist when the generic company has written the letter (offer) and is on the way to send it but have not put it in the mailbox yet. In this situation the generic company still has something more to do however the remaining thing is in close connec-

tion both to the action in itself, namely to offer the generic drugs but also in close connection in time since the generic company is on its way to post the letter.[138]

The above mentioned situations are only examples of what may constitute an attempt to offer generic drugs. However, since an offering in itself can be made in several different ways then an attempt to offer could in my opinion be made in equal amount of different ways.

7.3 Preparation and the "intention" and the "use of a tool"

In the Swedish Penal Code it is stated that "A person who, with the intention of committing or promoting a crime, presents or receives money or anything else as pre-payment or payment for the crime or who procures, constructs, gives, receives, keeps, conveys or engages in any other similar activity with poison, explosive, weapon, picklock, falsification tool or other such means, shall, in cases where specific provisions exist for the purpose, be sentenced for preparation of crime unless he is guilty of a completed crime or attempt."

If putting the above mentioned definition in relation to a preparation to offer generic drugs the generic company needs to have an intention to commit or promote an offering by presenting or receiving money or by using any tools in order to commit the offer of the generic drugs. If analyzing the definition of the rule a preparation may be at hand if the generic company presents or receives money or anything else *or* using any tools in order to commit the offer. Therefore it seems that the generic company does not need to do both a presenting and receiving of money and a using of any tools, it seems enough that one thing of the two is fulfilled. However, it is a requirement that the generic company have had an intention to commit or promote the offer.

In relation to the above stated grounds the question is therefore what would constitute such an intention taken by a generic company and further what kinds of things that the generic company is doing that would be seen as a "using of tools" that is particularly suited in order to commit the offer. During the investigation of what would constitute an actual offering in chapter five it was shown that the Swedish court somewhat discussed the concept of a preparation to offer the generic drugs made by the generic company. In this regard the court stated in both the Sertraline case and the Merck case that an application and discus-

[138] This reasoning is also supported by other authors in the field, see for example E.Ficks, T.Groop - Interimistiska förbud vid intrång i läkemedelspatent, p. 136.

sion with the TLV did not constitute an actual offering (5.2.5) but could be seen a preparatory action taken by the generic company to in the future offer the generic drugs to the pharmaceutical market. Unfortunately the rule regarding interim injunctions against an attempt or preparation was not implemented at the time when the Sertraline case was established and the court did not examine the concept of preparation any further. In the Merck case as well the court held that the generic company had made other things that was considered to be a complete offering of the generic drugs and did therefore not see any reason to investigate it further. The court has although given some hints that generic company's contacts with different authorities during the patent protected period could be seen as a preparation.

If first of all putting the intention criteria in relation to the above stated grounds in order for an intention to be at hand it seems in my point of view that the generic company needs to have a particular purpose with it`s taken actions, namely to in the future commit or promote an offering of the generic drugs. If the purpose with the taken actions is not to commit an offering of the drugs during the patent protected period then the criterion for an intention to commit or promote a crime (in this case the offering) stated in the Swedish Penal Code would probably not be fulfilled. Therefore the actions taken by a generic company in my point of view has to be made with the purpose to in the future offer the generic drugs.

When it comes to the listed tools stated in the paragraph it has been established that also a lawful use of any tools can be considered to be a tool to commit a crime if the tool is particularly suited for the actual crime (4.3.4). If applying this to the situation of an offering of generic drugs in my point of view that would probably mean that a generic company may use something that is particularly suited for the actual offering of the generic drugs. In this regard it therefore seems that in order for something to be considered to be particular suited in order to offer generic drugs the thing has to in some way be a helping tool in order for the generic company to be able to offer the generic drugs in the future.

7.4 May guidance be brought from Denmark in order to establish an attempt or preparation?

Although Denmark does not have a rule regarding interim injunctions against attempt or preparation the Danish cases have established principles on what kinds of evidence that may show that the generic company in the near future will commit a pharmaceutical patent

infringement. In the Danish cases the court established that the obtaining of a market approval for the generic drugs together with other circumstances could show a probability that the generic company would in the near future infringe the pharmaceutical patent.

The question is whether the actions taken by the generic companies could be applicable also to the definition of an attempt or preparation in the Swedish Penal Code. As been established in order for an attempt to exist the generic company has to start the execution of a crime (offering) but it has not been completed. The situation in the Danish cases however was that the generic companies had obtained market approvals for their generic drugs during the time there was a patent protection on the original drug. Since the application and obtaining of market approvals in itself do not constitute a pharmaceutical patent infringement then the actions would not in my opinion be seen as any attempt to the same either.

If looking at the specific situation in the Danish cases however it seems that the actions taken by the generic companies have been made more as a preparation by the generic companies in order to launch the generic drugs onto the market before the patent protection on the original drug has expired.

However, the question is whether some guidance may be brought from the Danish cases in order to establish a preparation in accordance with the Swedish Penal Code. As has been established a preparation should be deemed to exist when the generic company with an intention to commit or promote an offering is using any tools that is particularly suited in order to commit the offer. In the Danish cases the Danish court highlighted that a generic company's refusal to declare that they would not in the future infringe the patent gave a suspicion that the generic company in the future would just infringe the patent. In this case the refusal to declare such a thing could be seen as the generic company had an intention with its plans to obtain the market approvals, namely to later launch the generic drugs onto the market. The sign of an intention in this case was simply that the generic companies did not attempt to disprove the suspicions that they in the future would infringe the patent.

Further, the Danish court held that when a generic company has applied and obtained a market approval in a very early stage in comparison to when the patent protection expires (for example several years before the expiration of the patent) that could also indicate that the generic company was planning to market the generic drugs during the patent protected period. In this regard such actions could also indicate that the generic company has an intention to in the future infringe the patent.

The question is further whether any guidance in the Danish case law can be brought on the term "use of a tool" that is particularly suited in order to commit an offering of the generic drugs. In the Danish case law it was established that an application and obtaining of market approvals for the generic drugs together with the above mentioned circumstances showed enough probability that the generic companies would in the near future infringe the pharmaceutical patent. Since there is no possibility to launch the generic drugs onto the market if there is no market approval for the generic drugs then there is no possibility to infringe the pharmaceutical patent either if no market approvals have been obtained. In this regard the obtaining of a market approval in order to launch the generic drugs could be seen as a necessary thing in order for the generic companies to in the future infringe the pharmaceutical patent. In my opinion, and in this particular situation, the obtaining of the market approvals could therefore be seen as a needed tool that is especially suited in order for the generic companies to infringe the patent.

If putting this in relation to a preparation set out in the Swedish Penal Code in my point of view guidance may be brought from the Danish cases in order to establish such a situation. A market approval is a necessity to have in order to launch generic drugs also in Sweden it is therefore also a necessity to obtain a market approval in order to be able to infringe the pharmaceutical patent by an offering of the generic drugs. Therefore such administrative measures together with other circumstances that shows an intention (for example a refusal to declare not to infringe the patent) by the generic to obtain the market approvals in order to offer the generic drugs should in my point of view also be enough of evidence in order to establish a preparation in accordance with the Swedish Penal Code.

8 Final remarks

The purpose of this thesis was to investigate when a pharmaceutical patent holder may apply for an interim injunction against a generic company on the grounds of an attempt or preparation to offer generic drugs on the market. In this situation the pharmaceutical company must show a probability that the generic company is attempting or preparing to do so.

If first of all looking at the concept of an attempt it seems that an attempt to offer generic drugs could exist in many different ways. Since the term offering has been given a very wide interpretation and may include many different things then an attempt to offer could in my opinion exist in equal amount of ways. Although in order for an attempt to offer generic drugs would exist the generic company must have started the execution to commit the offer but the offer has not been completed. In my opinion it is therefore important that the actions taken by the generic company would lead to a complete offering or at least that it is a danger that it would lead to a complete offering in the end. Although there could not according to me be given any specific guidelines on how to establish an attempt (except for the definitions set out in the Swedish Penal Code) the example in chapter 7.1 could in my opinion constitute an attempt. In this situation an attempt would be deemed to exist in my point of view when the generic company has written a letter declaring that they want to sell the generic drugs and further send it to a pharmacy. In this situation the generic company has done everything according to their plan to offer the generic drugs and in the timeline between the sending of the letter and the pharmacy's receiving of the letter would according to me constitute an attempt to offer the generic drugs. This example is however only one of many possible situations of when an attempt to offer the generic drugs could exist and there is in my point of view no common definition that may be applied to them all.

When it further comes to establishing a preparation to offer generic drugs the intention by the generic company seems to play an important role in determining whether a preparation is at hand or not. Further, the "use of a tool" that is particularly suited for the actual offering. When it comes to establishing an intention it seems in my point of view that the generic company needs to have a particular purpose with its taken actions, in this case the purpose to offer the generic drugs before the patent protection period expires on the original drug. Further the company needs to engage in some kind of a tool in order to make the offering of the drug possible. In my opinion a preparation to offer the generic drugs could be more difficult to determine in comparison to an attempt since a preparation do not necessarily have to be in a direct connection to a specific offering. In this regard a generic com-

pany may have the intention and further take actions that are considered to be a tool to commit the offer a long time before the actual offering occurs. How to prove such an intention and further how to prove that a specific action have been particularly suited in order to commit the offer may therefore very well depend on the specific situation. Since an intention to do something may appear in many different ways and different things can be considered as helpful tools for different generic companies a common establishment of a preparation may in my opinion be somewhat difficult.

In my point of view the established situation in the Danish cases however could be in some aspects be equated to the definition of a preparation in Sweden. The generic companies refusal to declare that they would not in the future infringe the patent together with the obtaining of a market approval which is a necessity in order to be able to launch the generic products may in my opinion very well constitute an intention and use of a tool that is particularly suited in order to offer the generic drugs. Since also the obtaining of a market approval is a requirement in order to launch the generic drugs in Sweden such actions together with a proof that the generic company has an intention to obtain the market approvals in order to offer the generic drugs in Sweden may very well in my opinion constitute a preparation by the generic company to offer the generic drugs. In this regard I believe that the established principles in Denmark may be used as guidance in future interpretations in Sweden of what may constitute a preparation to offer generic drugs although Denmark do not have an explicitly stated attempt or preparation rule.

On the above mentioned grounds I believe that an overall assessment of the particular situation has to be made in order to establish a probability that an attempt or preparation is at hand. Although guidance may be brought from Denmark on how to establish a preparation a restrictive interpretation of the established principles in Denmark must be made.

List of references

EU regulations

Council Regulation (EEC) 1768/92 of 18 June concerning the creation of a supplementary protection certificate for medicinal products.

EU directives

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

Swedish legislation

Pharmaceutical Benefits Act (2002:160).

Swedish Medical Product Act (1992:859).

Swedish Patent Act (1967:837).

Swedish Penal Code (1962:700).

Danish legislation

Retsplejeloven (LBK nr. 1063)

Official publishing

NU 1963:6.

Prop. 1977/78: Part A Om ändringar i patentlagen m.m.

Prop. 1985/86:86 Om ändring i patentlagen m.m.

Prop. 1993/94:22 Om tilläggsskydd för läkemedel m.m.

Prop. 1994/95: 86 EG-regler om tilläggsskydd för läkemedel.

Prop. 2005/06:70 Om ändringar i läkemedelslagstiftningen.

Prop. 2008/09:67 Civilrättsliga sanktioner på immaterialrättens område – Genomförande av direktiv 2004/48 EG.

SOU 2008:20 Patentskydd för biotekniska uppfinningar

DS 2007:19

Case law

Swedish Supreme Court

NJA 2008 s.1192 (Sertraline)

Stockholm District Court

T 7-536-93 –/T 7-737-94 (Carboplatin)

Joined cases, T 16665-04, T 252-05, T 15175-05, T 7337-05, T 15141-05, T 30912-05, T13939-05. (Merck)

Danish Östre landsrett

B-1053-08 *Novartis AG and Novartis Healthcare A/S vs. Teva Denmark A/S, Östre Landsret, nr. B-1053-08, 18th of March 2008.*

FS 1-13061/2007 Eli Lilly and Company Ltd. And Eli Lilly Danmark A/S vs. Nomeco A/S, Retten på Frederiksberg, 28th of April 2008.

EU documents

Communication from the Commission to the Council, the European parliament and the Economic and Social Committee, Follow-up to the Green Paper on combating counterfeiting and piracy in the single market, [Brussels, 30.11.2000 COM (2000) 789 final].

Pharmaceutical Sector Inquiry Final Report – European Commission, Competition DG 8 July 2009.

Injunctions in Intellectual property Rights – European Observatory on Counterfeiting and Piracy.

Literature

Books

L. Holmqvist, M. Leijonhufvud, P.O. Träskman, S. Wennberg, *Brottsbalken – En kommentar, Del II (13-24 kap.) Brotten mot allmänheten och staten m.m, Studentutgåva 5, Norstedts Juridik AB.*

B. Domeij, *Läkemedelspatent – patent på läkemedel I Europa ur ett rättsvetenskapligt och rättsekonomiskt perspektiv,* 1998, Juridiska Instutionen, Stockholms Universitet.

B. Domeij, *Fokus på Patenträtten – En introduction till patenträtten*, 1997, Brand Eye AB, Stockholm.

Articles

E. Ficks, *Seeking Preliminary Injunction for Pharmaceutical Patent Infringement in Sweden – A comparative law analysis of pharmaceutical patent protection and injunction proceedings in the Nordic countries*,2009, Roschier.

R. Hilli & T.Groop, *Imminent threat of infringement*, July/August 2008, Nordic States: Biotechnology.

E.Ficks & Tom. Groop, *Interimistiska förbud vid intrång i läkemedelspatent,* Nordiskt Immateriellt Rättsskydd (NIR)/Nordic Intellectual Property Law Review, no. 2/2009.

D. Ramsjö, *Proportionalitetsprövningen vid interimistiska förbud i immaterialrätten,* 1/2009. http://www.juridiskpublikation.se/2b/?id=85.

M.Norrgård, *Immaterialrättens Sanktionssystem och Enforcement – Direktivet,* (NIR) 2004.

P. U. Plesner, C.Thufason – *Udviklingen af immaterialretten I Danmark*, NIR 2008, p. 529.

Internet sources

LIF:s FOU- enkät 2010, rapport 2011:1, Mars 2011. http://www.lif.se/default.aspx?id=61330.

L. Jonshammar - Karnov Internet, Constitutional commentary to the Swedish Patent Act (1967:837), 1:3 § first paragraph, point 3, number 26, last visited 18th of March. http://juridik.karnovgroup.se.bibl.proxy.hj.se/document/696290/1?versid=146-1-2005#SFS1967-0837_N26

P. Sande – Karnov Internet, Constitutional commentary to the Swedish Patent Act (1967:837), 9:57b § third paragraph, number 210, last visited 18th of March. http://juridik.karnovgroup.se.bibl.proxy.hj.se/document/696290/2?versid=146-1-2005#SFS1967-0837_N210