Patent Application Strategy in Europe for the Pharmaceutical Industry

How should pharmaceutical companies' patent application strategy change with the introduction of the Unitary Patent and the European and European Union Patent Court?

Victor Lerenius

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Supervisors

Jonas Ledendal

Hans Henrik Lidgard

LUNDS UNIVERSITET
Ekonomihögskolan

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Abstract

This thesis aims to establish how the introduction of the Unitary Patent and the European and European Union Patent Court will affect the pharmaceutical industry's choice of patent application route when applying for patents in Europe in the future. To establish the expected effect of the Unitary Patent on the industry interviews with a selection of professionals in the research and development industry, the public sector and a patent litigator have been carried out. The research and interviews has shown an array of advantages associated with the Unitary Patent, mainly of economic nature as an effect of reduced translation requirements and increased centralised administration but also we are likely to see that practice will eventually become more predictable within Europe. Many of the problems that remain to be established in the draft agreements have proven to be a major disadvantage to the Unitary Patent as it adds a dimension of uncertainty to the patent holder. The fact that Italy and Spain have chosen to opt out of the Unitary Patent project is unsurprisingly a major disadvantage to the project and the European Union as a whole. It has been concluded that the many uncertainties and the disadvantages already shown with the Unitary Patent the best recommendation to patent applicants in the future is to stay with the European patent or national patents to see how European and European Union Patent Court practice develops and how the will be perceived by the industry.

Keywords: Intellectual property, Patent protection, Litigation, Unitary Patent, European and European Union Patent Court, Patent application strategy.

Summary in Swedish

Denna uppsats syftar till att fastställa hur införandet av Enhetliga Patent och den Europeiska- och EU-patentdomstolen kommer att påverka läkemedelsindustrins val av patentansökningsförfarande när de ansöker om patent i Europa i framtiden. För att fastställa de förväntade effekterna av Enhetliga Patent på branschen har intervjuer med ett urval personer inom forskning- och utvecklingsföretag och en patentadvokat genomförts. Intervjuerna har visat en rad fördelar som förknippas med Enhetliga Patent, främst av ekonomisk karaktär, som en effekt av minskade översättningskrav och ökad centraliserad administration, men det är även sannolikt att vi kommer se att praxis så småningom kommer bli mer förutsägbar inom Europa. Många av de problem som återstår att fastställa i avtalsförslagen har visat sig utgöra en stor nackdel för industrin eftersom det tillför en dimension av osäkerhet för patenthavare. Det faktum att Italien och Spanien valt att ställa sig utanför samarbetet med Enhetliga Patent är givetvis en stor nackdel för projektet och Europeiska Unionen som helhet. De slutsatser som kunnat dras är till följd av osäkerheterna och de nackdelar som redan påvisats med Enhetliga Patent att den bästa rekommendationen för patentsökande i framtiden är att fortsatt söka europeiska patent och att se hur praxis utvecklas och hur europeiska och EU-patentdomstolen kommer att fungera i praktiken.

Abbreviations

CGEU	Grand Chamber of the EU
EEUPC	European and European Union Patents Court
EPC	Convention on the Grant of European Patents, also the European Patent Convention
EPLA	European Patent Litigation Agreement
EPO	European Patent Organisation
EU	European Union
EUCJ	Court of Justice of the EU
IP	Intellectual Property
M&A	Mergers & Acquisitions
Member States	Member states of the European Union
PCT	Patent Cooperation Treaty
Plc	Public limited company
PRV	Patent Office of Sweden (Patent- och Registreringsverket)
R&D	Research & Development
SPC	Supplementary Protection Certificate
TFEU	Treaty on the Functioning of the EU
Unitary Patent	European patents with unitary effect
UPLS	Unified patent litigation system
US	United States
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

1.1 Background

1.1.1 Pharmaceutical Industry

The pharmaceutical industry consists of companies that produce synthetically produced biological and chemical products that are used against illnesses among human beings. Despite this producers of for example diagnostic products such as nicotine replacement are frequently said to belong to the pharmaceutical industry as well. The global turnover for this industry in 2009 was 808 billion US$ and still growing by approximately 6-10% per annually.[1]

The pharmaceutical industry accounts for a large proportion of the world's patent applications. It has been shown that R&D within the pharmaceutical industry is driven to a large extent by the patent protection system. 60% of the innovations in this sector had never been realised without the protection of patents. This compares to the average of 6.7% in other industries.[2]

The pharmaceutical industry comprises of a small number of large companies and a large number of small companies. Medium sized companies are few and far between. This is mainly due to the high frequency of M&A's in this industry, which limits the small companies' ability to grow into medium sized ones.[3]

1.1.2 The Patent Cooperation Treaty and the European Patent Convention

Patent Cooperation Treaty (PCT) is an international treaty that has been in force in the first 20 countries since 1978. Since it was first drafted the treaty has been amended in 1979, 1984 and 2001. The treaty is currently signed by 144 countries.[4] PCT provides persons and companies of the member states the possibility to use the PCT international patent application system. An application is filed with the Receiving Office (RO), whom will carry out an initial search for the applications patentability. The application can then, upon request, and payment of the relevant fees be forwarded for national application. The

[1] IMS Health website, 2011-10-05

[2] Mansfield, E. Management Patents and Innovation - An Empirical Study, Management Science 1986, p. 175

[3] Domeij, Bengt, Patenträtt, 2007, Iustus förlag, p. 1 ff.

[4] www.wipo.int/pct/guide/en/gdvol1/annexes/annexa/ax_a.pdf, 2011-09-23

initial search carried out by the PCT can then be used by the national patent offices but is, however, not binding. The PCT has a number of minimum requirements for the patent application and in the articles of the PCT outline the rights and requirements of a patent holder, which also forms the backbone of the EPC (see 2.1 below). Most countries require translations in order for an application to become valid. Essentially, the PCT application provides the applicant with a priority date and a search report. It must then be forwarded to national patent offices to become valid patents in the various states. For this reason the PCT application system will not be further discussed in this essay but should to be addressed as it forms the backbone of the European patent system.[5]

1.1.3 Patent application in Europe

When a person applies for a patent in Europe it is possible to choose different application routes. Firstly, it is possible to apply using the national application system in each country separately according to the rules and regulations of that particular country.

Secondly, it is possible to choose to apply for a European patent at the EPO. The application can then be granted by the EPO and during a nine month opposition period also be challenged. After this period, however, it can only be individually challenged in the patent's designated states.[6]

Discussions on implementing a Unitary Patent in Europe are being held at the EPO, the EU Parliament and the EU Council. This will open up for a new means of applying for a patent in Europe. The Unitary Patent will be valid in all or some of the countries taking part. The only court to have jurisdiction over these patents in their entire lifetime will be the EEUPC. This way the patent application system and litigation system will be centralised in Europe.

1.2 Purpose and Research

The implementation of a Unitary Patent will open up for an additional choice for patent protection in Europe. The purpose of this essay is to evaluate the pros and cons of the Unitary Patent versus the European patent. The conclusion of the evaluation will lead to a recommendation as to which patent will be the most advantageous to the pharmaceutical industry. This essay aims to target pharmaceutical companies in both Europe and outside of Europe that need advice about the European patent systems that will be available in the future, by suggesting a strategy.

1.3 Limitations

This thesis focuses on the pharmaceutical industry's strategic decision of which European patent system to choose when applying for a patent now and in the near future. The Unitary Patent will be compared to the European patent and the national patent application route in general and does not contain any comparisons to other application

[5] Tankha, Ash, Patent Your Idea, p. 266 ff.

[6] http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar99.html

systems apart from what has already been mentioned about the PCT since the PCT route essentially has the same effect as applying for patents nationally.

The essay is essentially limited to the pharmaceutical industry since this is a very R&D intensive industry where generic companies look very closely at the patents filed by these companies and infringements are common. The essay is, however in many aspects also valid for other R&D companies.

I will focus on the differences between the European patent and the Unitary patent. I will not further study the differences between the different national application systems nor compare these to each other.

Since the drafts of the Unitary Patent, translation agreements and the EEUPC are not finalised, changes in the drafts have been considered up to and including 7 December 2011, and this will for the purpose of the essay be regarded as the final draft version. Any background information, analyses, arguments and conclusions will be based on this.

Although the issue of how the drafts should be *changed* in order to benefit the pharmaceutical industry better is very close at hand and is very interesting, this topic will not be discussed in this essay apart from what is mentioned in the interviews in Appendix 1.

1.4 Methodology and Materials

In order to establish whether to apply for a Unitary Patent or not once this choice is available it is necessary to study a number of aspects that might affect this determination. Therefore I will study the following aspects of the current patent system and compare this to the Unitary Patent. Other aspects have been regarded to not have a noteworthy effect on strategic decisions.

- Application
- Translation and costs
- Time aspects
- Litigation and appeal
- Preliminary Injunction

A couple of cases have also been chosen. The cases aim to shed light on the problems with the current patent system in order to establish how these deficits can be overcome with the Unitary Patent. The purpose of the *Epilady* case is to illustrate how two courts can come to different conclusions with the same infringement and the same patent and how this problem relates to the patent applicant and the choice of application strategy. The *Esomeprazole* case has a similar purpose but concerns validity and not infringement.

With the objective to establish what the main concerns are with the current draft of the Unitary Patent and the EEUPC. I have interviewed a number of professionals in the field whom work in the field. Summaries of the interviews are available in Appendix 1 below.

The interviewees are as follows:

- Andrew Farquharson, Director of External IP Affairs, AstraZeneca UK Limited
- Sally Field, Partner at Bristows (Services) Plc. and external teacher in Intellectual Property Law at Oxford University
- Fredrik Egrelius, Senior Patent Attorney, Ericsson AB
- Benjamin McDonald, Senior Patent Director, AstraZeneca UK Limited
- *Anonymous*[7] External IP Affairs Manager at a major European pharmaceutical company
- Susanne Sivborg, Director General and President, PRV

The interviewees have been chosen as they represent different areas of expertise. The interviewees are both from within the pharmaceutical industry and from other industries. There are patent attorneys, lawyers and also Susanne Sivborg from the Swedish Patent Office, PRV.

1.5 Outline

The essay consists of five chapters. Chapter one is an introduction to the essay. Some important limitations to the essay are also outlined in this part.

Chapter two and three bring up relevant aspects of the current European application system and the draft agreement of the Unitary Patent including the EEUPC respectively.

The analysis is carried out in chapter four. It firstly outlines some problems with the current patent system by briefly describing two cases. Following this is an analysis of the differences between the European patent and the Unitary Patent.

Chapter five gives the reader conclusion and recommendations as a result of the analysis.

The interviews have been summarised in Appendix 1.

The following two appendices contain information and a summary of the two patents that the cases in chapter four concern.

[7] This interviewee has chosen to be anonymous in this essay for a number of reasons.

2 European Patent Protection today

2.1 The European patent

Convention on the Grant of European Patents (EPC) is a lateral cooperation between (to date) 38 states, of which all EU-members are included. The purpose of the convention is in line with the PCT to simplify the application system, but the EPC goes much further in fulfilling this role. Belgium, Luxemburg, Switzerland, the UK and West Germany were first to ratify the convention in October 1977. Sweden was the first country to sign the convention after these countries some six months later.[8]

The *European Patent Organisation* (EPO) embodies the convention. The EPO is always subordinated the rules and Articles of the EPC. The EPO handles the European patent applications and administers the payment of various fees from patent applicants.

Bosnia & Herzegovina and Montenegro have not yet joined the EPC. Instead they have so called *extension agreements* with the EPO, which enables patent applicants to, with the payment of a fee, apply for a patent also in these countries but the application is forwarded to the countries' patent offices for validation. Eight of the eastern European countries have previously had *extension agreements* but have since decided to join the EPC.

2.1.1 Validation

The EPO comprises of 38 countries of which 27 are EU Member States. The EPO examines patent applications and, provided the relevant conditions are fulfilled, also grants European patents. In order for a granted patent to become effective in a Member State, validation must be requested for each country where patent protection is sought and the relevant application fees paid.[9]

2.1.2 Languages and translation arrangements

The EPO has three official languages, namely German, French and English. In order for patents to become valid in countries with other first languages, translations must be filed by the applicant. This is a costly procedure to the applicant. This problem does not exist

[8] www.epo.org/about-us/organisation/member-states.html, 2011-07-28

[9] [9] IP/11/470, *Commission proposes Unitary Patent protection to boost research and innovation*, Brussels, 13 April 2011, p. 1

in other large markets such as the U.S.A., where no language barriers are present. More about how this problem will be overcome when introducing the Unitary Patent.

For a European patent to be validated in a Member State, national law in some countries require a translation from the patent applicant in the official language of that particular Member State. With the purpose of decreasing the cost of translations the so-called "London Agreement" is in force since 1 May 2008 in eleven EU Member States. For these countries translation requirements are somewhat cut.[10]

2.2 Supplementary Protection Certificate

An SPC can be granted for medicinal products for human and veterinary use. The certificate takes effect at the end of the lawful term of the basic patent and is valid for a period equal to that which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years.[11] This possibility will not affect the introduction of the Unitary Patent apart from that the same protection must apply for all member countries at all times.

[10] *Agreement on the application of Article 65 EPC*, OJ EPO 2001, p. 550

[11] Council Regulation (EEC) No 1768/92 concerning the creation of a supplementary protection certificate for medicinal products, 18 June 1992

3 The Unitary Patent and the European and European Union Patent Court

3.1 The Unitary Patent

The existing European patent system has a range of problems, namely that it is very costly to obtain a patent in all countries in Europe, translation costs and in addition the litigation costs can be very high. Furthermore, litigation can take place in several different countries simultaneously, sometimes also with different outcomes. It is for these reasons that the Unitary Patent is to be implemented in Europe in the near future.

In order to overcome the problems of the current system Unitary Patents will become available to patent applicants in Europe. These patents will be applied for with the EPO and if granted will be valid in all countries assigned upon application. A new court is to be established which will have exclusive jurisdiction for the Unitary Patents. It is suggested to be called the European and EU patent court (EEUPC, see 3.2 below).[12]

Negotiations are being held in the EPO and EU Council with the goal of registering the first Unitary Patents in 2013. Italy and Spain have opted out of the project and will not be included in the Unitary Patent scheme. Instead patents will be national in these countries and decisions made by EEUPC will have no effect in these countries. The reason they have opted out is mainly due to that the official languages are only French, English and German. The European Commission published in April of 2011 two draft regulations. The first regulates the Unitary Patent and the translation arrangements of the same.[13]

The language problems have caused many previous discussions to fail without an agreement. The varying perspectives of the best rule of law and procedural rules have also caused many discussions to fail.[14] The last proposal 2011/93 to an EU regulation on Unitary Patents is due to be agreed on by EU institutions in February 2012.

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[12] http://www.epo.org/law-practice/legislative-initiatives/eu-patent.html, updated 2011-11-15

[13] COM(2011) 215 final (2011/0093 (COD)) Proposal for a Regulation of the European Parliament and of the Council implementing enhanced cooperation in the area of the creation of Unitary Patent protection, Brussels, 13 April 2011

[14] Morton, J. *The Proposed European and EU Patents Court(EEUPC): Real Progress At Last*, 2009-12-22, s. 2

Unitary Patents can only be granted, transferred, revoked or lapse in the whole territory at the same point in time, which reduces costs but is naturally less flexible.[15]

3.2 European Patent Litigation Agreement and European and European Union Patent Court

The European Patent Litigation Agreement (EPLA) is a project not yet implemented that aims to establish a European and EU Patent Court (EEUPC) with exclusive jurisdiction of Unitary Patents.[16] One of the main problems over the last decade has been to ensure the court is compatible to the TFEU[17]. The various drafts drawn up so far have not been compatible with TFEU and have thus not been accepted by the EU Council and EU but the current draft, not yet accepted, is, however regarded to be compatible. The main problem with the drafts so far drawn up have been that countries not members of the EU, but members of the Unitary Patent scheme are permitted to affect decisions that have effect within the EU, which is not allowed by the TFEU.[18] This has been resolved by treating EU-members' patents separately from non-members.

The main benefits of the Unitary Patent are the unitary character, which provides uniform protection and has an equal effect in all participating Member States. A Unitary Patent may be limited, licensed, transferred, revoked or lapse with effect in all participating Member States at the same point in time.[19]

3.2.1 Eligibility and legal effect of the European and European Union Patent Court

The EEUPC will have exclusive jurisdiction over the Unitary Patents. But as the draft stands now Spain and Italy will not participate and thus any judgements by the EEUPC will have no legal effect in these two countries.

The purpose of the EEUPC is to deal with disputes concerning validity and infringement of European patents. The two benefits are expected to be firstly identical rulings throughout Europe. The economic benefits are also apparent since all resources can be used in a single litigation at the EEUPC as opposed to litigating in several Member States. These disputes are often very complex and drawn-out and can therefore take several years. It is therefore increasingly becoming important to have an efficient strategy

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[15] 2011/0093 Proposal for a regulation of the European Parliament and of the Council *implementing enhanced cooperation in the area of the creation of Unitary Patent protection*, p. 3 and 2011/0094 Proposal for a regulation of the European Parliament and of the Council *implementing enhanced cooperation in the area of the creation of Unitary Patent protection with regard to the applicable translation arrangements*, p. 3

[16] Faktapromemoria 2006/07:FPM76: *Meddelande om förbättring av patentsystemet i Europa*, 8 May 2007

[17] Consolidated version of the Treaty on the Functioning of the European Union, Official Journal of the European Union, 9 May 2008

[18] TFEU Article 218.

[19] COM(2011) 215 final (2011/0093 (COD)) Proposal for a Regulation of the European Parliament and of the Council *implementing enhanced cooperation in the area of the creation of Unitary Patent protection*, p. 5

for how these lawsuits and claims will be designed for the long-term to provide better protection for their innovations and products.[20]

Whilst Italy and Spain have opted out of the Unitary Patent and EEUPC project European litigation in these countries must be taken care of separately from the rest of the EU (and the other EPO countries not members of EU) and may have a different outcome to that formed by the EEUPC.

The location of the court is yet to be determined but is likely to be in Munich, Paris or in London. This has also been widely debated among various stakeholders. A decision on this was supposed to be made in mid-December but was postponed.

"Essentially the whole package is negotiated, it's final. Nevertheless, due to the resistance to compromise of one or two member states, we will not decide this year on the seat of the court… This is an issue where we have just hit the wall", Mikolaj Dowgielewicz Poland's European Affairs Minister.[21]

3.2.2 Instances of the European and European Union Patent Court

The EEUPC will according to the last draft be made up from a series of Local Divisions in various parts of Europe and a Central Division and the Appeal Court based in a location, not yet determined.

Articles 6 and 8 as the draft stands at the moment and to ensure compatibility with the EC Treaty and article 267 of the TFEU the EUCJ will have final jurisdiction.

The Central Division and Appeal Court will be made up from three judges and two technical experts. All judges in the EEUPC are to have a high degree of specialisation in patent litigation. The competence is to be kept up to date through centralised education.[22]

3.2.3 Language of hearings in the European and European Union Patent Court

The language of the proceedings will be either the national language of the Local Division's country or alternatively it may be one of the three official languages of the EPO, namely German, English or French. The language of the hearing at the Central Division should, if possible, be the same as that of the first hearing. Oral testimonies will be limited and the goal is to complete the hearing within one day.[23]

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[20] Morton, J. *The Proposed European and EU Patents Court(EEUPC): Real Progress At Last,* 2009-12-22, s. 2

[21] Hayden, J., Bloomberg, 2011-12-16
www.bloomberg.com/news/2011-12-16/agreement-on-eu-wide-patent-unlikely-this-year-poland-says.html,

[22] Morton, J. *The Proposed European and EU Patents Court(EEUPC): Real Progress At Last,* 2009-12-22, s. 3

[23] Ibid, s. 3 f.

3.2.4 European and European Union Patent Court and competition law

On the 4th of October 2009 the Competitiveness Council[24] published their views on the Unitary Patent. It was then ruled that Unitary Patents and the EEUPC may not override the rules set out by the European competition law. Since this publication several issues were still to be determined, especially concerning the UPLS and since the drafts have been revised several times the Competitiveness Council held on 29 September 2011 an exchange of views on the UPLS. Part of the discussions was to determine the compatibility of the draft with the EUTF. Under the Polish Presidency the Council came to the conclusion that they were sufficiently reassured of the compatibility. The Competitiveness Council will thus continue working towards reaching a political agreement on the Unitary Patent and the EEUPC by the end of 2011.[25]

[24] A Council of the EU created in June 2002 through the merging of three previous configurations Internal Market, Industry and Research

http://consilium.europa.eu/policies/council-configurations/competitiveness

[25] 17539/11 *Draft Agreement on the creation of a Unified Patent Court - Guidance for future work*, Polish Presidency of the Council of the European Union, Brussels, 24 November 2011, p. 1

N.B. This goal was not met as the signing of the agreement scheduled for the 22 December 2011 was postponed and the Danish Presidency will now continue the work from where the Polish Presidency ended. The vote has been scheduled for February 2012.

4 Comparison of the Unitary Patent and the European and European Union Patent Court

4.1 Cases

4.1.1 The Epilady cases

The Epilady cases are an illustration of how courts in different EPC states can come to conflicting conclusions on the same actual patent.

The cases concern an alleged patent infringement by Remington Consumer Products Ltd. (Remington). The patent proprietor was Improver Corp. (Improver) whom had invented a hair remover. A patent was granted on 13 June 1990.[26]

The patent was applied for in Austria, Belgium, Switzerland, Germany, Spain, France, the UK, Greece, Italy, Lithuania, Luxemburg, the Netherlands and Sweden.

Improver sued Remington in five of these countries. The case was taken up by courts in Germany[27], the Netherlands[28], Italy, Austrian and the United Kingdom[29].

Varying interpretations of the patent claims resulted in the German, Dutch and Italian courts ruling there was infringement in the patent whereas the British and Austrian courts had a conflicting view, ruling there was no infringement.[30]

4.1.2 The Esomeprazole cases

The Esomeprazole cases[31] show how rulings by the EPO can have a conflicting outcome to that of national courts.

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[26] EPO patent application EP 89102779.9 led to patent EP 0330091 A3 being granted. The abstract and the patent claims have been included in A3.2 and A3.3 respectively.

[27] Dusseldorf Court of Appeals, 21 IIC 572 (1990)

[28] The Hague Court of Appeal, 21 IIC 586 (1990) and The Hague District Court, 21 IIC 589 (1990)

[29] UK Court of Appeal, 21 IIC 561 (1990) and UK Patents Court, 21 IIC 860 (1990)

[30] COM(2007) 165, Communication from the Commission to the European Parliament and the Council - Enhancing the patent system in Europe, p. 6 and also J., Pagenberg 24 IIC, 1993, p. 314-345

The dispute was an application for revocation and nullification of the patent EP 1 020 461 B1[32] of an alkaline salt of the (-)-enantiomer of omeprazole[33] for the manufacture of a pharmaceutical, which treats gastric acid related diseases on the grounds of

- extension of the granted subject-matter beyond the content of the application as originally filed (A. 100(c) in relation to A. 123(2) and A. 76(1));
- the invention was not sufficiently disclosed (A. 100(b));
- lack of novelty of the granted subject-matter (A. 100(a));
- lack of inventive step of the granted subject-matter (A. 100(a)); and
- it was also stated that: the granted subject-matter was not entitled to priority.

The dispute was handled by the EPO and the District Court of the Hague simultaneously. The patent was revoked by the EPO on 29 July 2011 after an oral hearing on the 9 June 2011.[34]

The same patent was ruled valid after the Dutch court rejected the claims for nullification of three generics companies as a result of a hearing in the District Court of the Hague. The latter decision was published on 6 July 2011.[35]

4.2 Application

The application procedure will not look very differently to the applicant choosing between the national patents via the EPO and the Unitary Patent via the EPO. The main difference when it comes to the application phase is that the national Registration Offices cannot be used for a Unitary Patent. The national Registration Offices will thus not have jurisdiction over these applications or over the patents, once granted.

Since Spain and Italy have opted out of the Unitary Patent these countries must be applied for separately from the other countries. Since these countries make up a substantial part of the European market this is likely to affect the filing strategy of many patent applicants.[36]

When applying for a Unitary Patent the flexibility of applying only in a few countries is diminished. The patentee must definitely take this issue into consideration when applying for a patent.

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[31] Application no. EP89102779.9 led to the divisional EPO patent no. EP 1020461 B1 of EPO patent EP 0 652 872 B1. The claims and abstract of the patents have been included in A3.2 and A3.3 respectively. The cases are likely to be appealed and the cases will then be taken up again in 2012.

[32] The District Court of the Hague handled the case of the Dutch part of the said patent. The EPO handled the application for revocation of the said patent.

[33] The (-)-enantiomer of omeprazole is called esomeprazole.

[34] EPO application no. 00 108 480.5

[35] District Court of the Hague 369137 / HA ZA 10-2189 and 372087 / HA ZA 10-2658

[36] Sivborg, see A1.6.4 and Farquharson, see A1.2.2.

4.3 Translation and costs

The current European patent system is very expensive, especially when including the national costs incurred once the patent has been granted. It can also be regarded as rather complex since all European countries have their own patent laws and ensuring these laws are obeyed is costly as well. The fact that the patent system is both expensive and complex is widely recognised as an obstacle to European innovation. Other markets such as U.S.A., Japan and China have much less complex systems and also much lower patent costs.

Discussions regarding the translation arrangements of the UPLS have caused discussions on implementing Unitary Patents to stagnate several times in the past. This has also been the main reason why Spain and Italy have chosen not to join the project. Spain claimed that the proposed system went against the spirit of the EU treaties that treat all EU languages as equal. Spain also claimed this was a political decision.

"*If the decision is to make the system more efficient, then only English should be used*", Juan Fernando López Aguilar said in a European Parliament Debate on 15 February 2011. [37]

The proposal to use the enhanced co-operation method was backed by 471 votes to 160 at the daily voting session at the European Parliament on 15 February 2011.[38]

The application process incurs considerable translation and administrative costs, which have been estimated to approximately €32,000 when applying for patents in the 27 European Member States. €23,000 out of this sum arises from the translation fees. As a comparison, an average US patent costs approximately €1,850. This means that a European patent costs around 17 times more, and this excludes the non-EU members. The actual overall validation costs are estimated to be around €193,000,000 per annum in the EU.[39]

Translation costs account for 40-65% of the total costs of a European patent application. When applying for a patent in all 34 EPO member states the patent must be filed in 24 different languages. Translation costs are not only incurred during the application phase but will also inevitably arise later, partly from the renewal but also especially if the patentee files for licencing or there are any infringements.[40] The translation issues are not only costly, but also time consuming.[41] More about the time issue in section 4.4 below.

Since a patent can be renewed, licensed, revoked or transferred separately in all different countries where the patent is valid this must be done for each country separately, should

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[37] López Aguilar, Juan Fernando, European Parliament debate, 15 February 2011, from 31:22

[38] Hajdú, Márton, *EP backs unitary European patent*, 15 February 2011

[39] COM(2011) 215 final (2011/0093 (COD)) Proposal for a Regulation of the European Parliament and of the Council *implementing enhanced cooperation in the area of the creation of Unitary Patent protection*, p. 1

[40] Ghosal, Vivek, Reforming Rules and Regulations, p 63 f. and 76

[41] Egrelius, see A1.4.1.

this be necessary. This is, not only costly but also time consuming and tedious. On the other hand this adds some flexibility to the patent holder who can choose to treat the patent differently in different countries. [42]

The London agreement, which entered into force on the 1 May 2008 and which has been ratified by a dozen countries does decrease the translation costs but they still account for a considerable part of the total costs.[43]

The Unitary Patent is estimated to cut the cost for obtaining a patent in all Member States by up to 80%, when taking the translation costs into consideration.[44]

4.4 Time aspects

It is difficult to rightfully establish with certainty how the time aspects of litigation suits are likely to look in the EEUPC. This must be seen by practice.[45] It is, however, likely that we will see the EPO and the EEUPC initially will be shocked over the increased work load, which inevitably will face them as a consequence of an increasing number of Unitary Patents being granted.

The application times are likely to be reduced with the Unitary Patent compared to the European patents when comparing applications to several countries. This will be mainly thanks to the reduced translation requirements.[46]

4.5 Litigation and appeal

There will be a transition period for European patents of five years in which a litigation procedure can be brought before either the EEUPC or before national courts. This can be both advantageous and a setback for the patent holder (of a European patent), whom may find that the procedural rules and legal application of laws may vary and affect the outcome of a suit.[47]

One of the main uncertainties yet to be determined regarding the litigation is the location of the Central Division. London, Paris and Munich are all fighting to become hosts for the Central Division.[48] The decision was to be made in December 2011 but has now been

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[42] IP/11/470, *Commission proposes Unitary Patent protection to boost research and innovation*, Brussels, 13 April 2011, p. 1

[43] van Pottelsberghe de la Potterie, Bruno & Mejer, Malwina

[44] Ibid, p. 1

[45] Farquharson, see A1.2.3.

[46] 2011/0093 Proposal for a regulation of the European Parliament and of the Council *implementing enhanced cooperation in the area of the creation of Unitary Patent protection,* p. 2 ff.

[47] *Draft Agreement on the creation of a Unified Patent Court - Guidance for future work* (17539/11), Brussels, 24 November 2011, p. 5.

See also Sivborg A1.6.5 and A1.7.2. Also, compare the different outcomes of the cases in 4.1.

[48] Farquharson, see A1.2.2 and also A1.7.2.

postponed to 2012.[49] This adds additional uncertainty to the litigation procedures in the Central Division. Depending on the location the procedural rules are likely to differ. It is currently not clear whether cross-examination of witnesses will be permitted or not.[50]

The experience and specialisation of judges increases the certainty and fairness brought by patent courts. It is important to patent holders to have high quality patent courts that handle patent litigation. Although, this has been established in the draft agreement, the question cannot be avoided. With new courts being set up around Europe it will be a difficult task ensuring this is fulfilled.[51]

4.5.1 Forum Shopping

At the moment several patent courts have jurisdiction to handle the same litigation, although sometimes court rulings will only be valid in a certain region. This fact has led to Forum Shopping, which is where the patent holder can chose at which courts to take up the case so that the decisions are more likely to be in its favour. Aspects such as, the qualification and experience of the panel, litigation costs and time aspects affect the courts chosen. Forum Shopping is according to the European Commission a threat against the legal certainty for patent litigation in Europe. Forum Shopping should not be possible for Unitary Patents but the industry does not completely agree to this.[52]

Forum shopping will be limited for European patents after the five year transition period. The EEUPC will be the only option after this period. This may to some extent be a disadvantage to the patent holder.

4.6 Preliminary Injunction

The regulations regarding preliminary injunction are not proposed to change significantly from any national regulation today with the introduction of the Unitary Patent. On the other hand, any filings of preliminary injunction being sought in any part of the EU must be granted by the EPO and will be valid in all countries. Although this is not a problem as such, it will mean that the increased number of applications for preliminary injunction to be handled by the EPO is likely to cause severe delays. This is a major concern of the industry as the draft stands at the moment.[53]

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[49] *Central Division seat decision may be delayed until 2012*, IPKat weblog, 20 December 2011, http://ipkitten.blogspot.com/2011/12/recap-update-unitary-patent-system-and.html

[50] Farquharson, Egrelius and Sivborg, see A1.2.2, A1.2.3, A1.4.2 and, A1.6.5. See also A1.7.2.

[51] Farquharson, see A1.2.3.

[52] Communication from the Commission to the European Parliament and the Council - Enhancing the patent system in Europe, COM(2007) 165, p .6
See A1.7.2.

[53] McDonald and Farquharson in particular, see A1.5 and A1.2.

All patent systems should have an assumption of validity. This essentially means that the patent holder must be regarded as the lawful owner of a valid patent and if the invalidity of a patent in litigation cannot be fully demonstrated, the patent must prevail and the validity of the patent should be assumed.[54] This might not, however, become the case in the new courts the pharmaceutical industry fears.[55]

[54] Managing Intellectual Property, Issue 197, p143-144

[55] See A1.5 in particular.

5 Conclusions[56]

The current patent system in Europe has many problems. Many of them have been overcome by the unified application system that is offered by the EPO. Nonetheless, once the application has been granted a patent has been issued in the various states that have been applied for it can be challenged. If no settlement can be reached prior to trials this must be resolved at the courts of each country. This means that there may be several parallel hearings as there is no regard taken to this issue. Witnesses or experts must thus make the same testimony several times in accordance to the procedural rules of each state. Not only is this costly and time-consuming but it also has the risk of resulting in contradictory outcomes in different courts.

The advantages with the Unitary Patent and the UPLS are many but the main setback at the moment is definitely the uncertainties. The procedural rules of the EEUPC, the location of the Central Division, the level of expertise of judges, how the translation arrangements will work in reality, the transition period and how practice will develop are the main uncertainties but there are many more.

The strategic recommendations to the pharmaceutical industry regardless of company size must inevitably be to wait. Since the uncertainties are too vast for any patent applicant in the pharmaceutical industry I would suggest to stay with the European patent system in the first couple of years of the Unitary Patent scheme in order to see how the uncertainties settle and how the UPLS is perceived by patent applicants and how practice develops.

The advantages that will eventually be brought with the Unitary Patent and the UPLS will surely outweigh the disadvantages that are present today.

[56] Conclusions are made taking into consideration draft changes up to and including 7 December 2011. As the drafts change and more uncertainties are established the conclusions and strategic recommendations will change accordingly.

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Appendix 1 Interviews

A1.1 Interview questionnaire

The following questions have been posted to the interviewees.

1. What are your three main concerns with the Unitary Patent including the translation arrangements as the proposal stands today (7 December 2011)?

2. What are your three main concerns with the Unitary Patent Court (EEUPC) as the proposal stands today (7 December 2011)?

3. What are, from your perspective, the three main advantages and disadvantages of applying for a Unitary Patent compared to applying for national patents or using the EPO model as it operates today? (In terms of flexibility, handling times, costs, enforcement, procedural rules, interim measures etc.)

A1.2 Andrew Farquharson, Director of External IP Affairs, AstraZeneca UK Limited

A1.2.1 The Unitary Patent and the translation arrangements

This is not Farquharson's area of expertise and he has therefore refrained from answering this question. This is a question for patent attorneys.

A1.2.2 The European and European Union Patent Court

There is still a lot still to be decided on the details of the court.

Farquharson fears there will be a low experience among judges in the panels.

Patent proprietors will be forced into litigating in one location, at a particular court.

The EEUPC will not be part of the EU in its entirety, which could potentially be a problem.

The location of Central Division is yet to be determined. Paris is less experienced and is a bad choice.

Bifurcation will become an issue.

Discovery is not permitted in France, whereas in UK this is permitted. As it looks now chances are there will be no discovery.

Cross examination of witnesses is an important issue that depending on if this will be permitted or not could cause major changes in the proceedings.

Articles 6 to 8 of the draft of the EEUPC apply to the ECG. Any appeals that are directed to the ECG are likely to be delayed. The CGEU are not qualified to handle infringement litigation.

A1.2.3 Comparison

Draft not finalized, which makes it difficult to make a rightful comparison.

Inexperienced courts can knock out patents worth millions of Euros.

It is likely to take a long time before the system is well implemented.

The Local Divisions will need to be set up quickly and competent, which is unlikely to go smoothly.

The location of the Central Division will have a big effect on the Unitary Patent and the EEUPC.

It remains to see how Biotech cases will be handled as they are treated very differently at present in for example Germany and the UK.

Farquharson recommends opting out for at least seven years.

A1.3 Sally Field, Partner at Bristows (Services) Plc and external teacher at Oxford University

A1.3.1 The Unitary Patent and the translation arrangements

This is not Field's area of expertise and she has therefore refrained from answering this question. Lawyers are not so concerned with this, this is a question for patent attorneys.

A1.3.2 The European and European Union Patent Court

The proposal is unclear in terms of infringement.

Field's compares the patent litigation to that of trademarks. It will become more similar and that has not worked out very well as tremendous delays and inconsistency have proven to be the consequence.

The fact that the EUCJ will have jurisdiction over the patent cases will mean that complex legal issues added to the already complex technical issues can mean the litigation will be very time consuming (when the EUCJ have jurisdiction).

It will be difficult to reconcile.

The technical complexity of patent cases makes them unsuitable for the EUCJ.

Not all EU members have joined the project, which complicates the process.

The funding of the project, since it is not a complete EU issue gives insecurities to the project.

Infringement and validity hearings are currently not the handled in the same courts in Germany and Eastern Europe. If this separation will be made in the divisional courts remains to be seen.

It is possible to see that all applicants continue to file nationally even after the introduction of the Unitary Patent.

The procedural rules of the court have yet to be established. It stands between the Continental versus Anglo-Sax procedural rules.

The funding of the courts also remains an uncertainty. Will the national patent courts be replaced all together?

How the privilege protection will be applied is also a crucial issue.

A1.3.3 Comparison

Once the Unitary Patent is given time to establish and settle in Europe and the procedures are good, then the advantages of the Unitary Patent will outweigh the disadvantages.

The system is likely to be fairer to all parties. Higher degree of certainty can develop.

It could potentially be very efficient.

Litigation and validity hearings can take place in one as opposed to say 20 countries.

The patent proprietor wants to know before entering a litigation or validity hearing what the risks are.

There is likely to be considerable saving of cost for patent proprietors.

The Polish presidency has given up today[57]. The Danish presidency will now take over implementing the Unitary Patent and the EEUPC. The Political intransigents are remarkable.

[57] 19 December 2011.

A1.4 Fredrik Egrelius, Senior Patent Attorney, Ericsson AB[58]

A1.4.1 The Unitary Patent and the translation arrangements

The translation arrangements will in many cases lead to both high costs and practical problems. This is also likely to cause delays, especially in the first years.

Substantive patent law is included in the Unitary Patent regulation.

A1.4.2 The European and European Union Patent Court

The Rules of Procedure are unknown and will be approved after the adoption of the regulation and agreement. The Rules must be in a finalised draft before the draft is accepted, which will not be the case if voting is carried out in February as scheduled.

The suggested financing of the courts will lead to too high fees for the parties.

The arrangements for the panels of the court must be altered so that truly multinational and technically experienced judges are represented in all panels.

The possibility of splitting the infringement and validity of the same patent is not acceptable. Cases of this nature should be handled at the same time, in the same court by a single panel.

The rules of representation must be clarified and the attorney-client privilege must be more clearly outlined.

A1.4.3 Comparison

A Unitary Patent and a common court system is important, but the drafts are unacceptable and must not be enacted in their current form.

The current drafts do not provide even a slight improvement to the current system, they provide a system which is inferior in comparison.

Political ambitions to conclude the legislative work in a hurry must not result in the system obtaining a structure which does not meet the needs of the users.

We have waited for decades, so what's another year?

[58] Ericsson AB has a number of concerns with the current draft of the Unitary Patent. Although Ericsson AB is not a pharmaceutical company many of the issues apply to the all R&D companies. The views of Nina Macpherson, Senior Vice president & General Counsel at LM Ericsson have also been included in the interview.

A1.5 Ben McDonald, Senior Patent Director, AstraZeneca UK Limited

A1.5.1 The Unitary Patent and the translation arrangements

The importance of *assumption of validity* when outlining the Unitary Patent is of great importance.

Preliminary injunction must be handled quickly and again it must be assumed that the patent proprietor's position will have the advantage over any infringing party if evidences are vague.

The goal of the Unitary Patent must be to benefit society more broadly and not only R&D companies.

A1.5.2 The European and European Union Patent Court

This is not McDonald's area of expertise and he has therefore refrained from answering this question.

A1.5.3 Comparison

The Unitary Patent will with confidence in time become the favourable option to our company but given the uncertainties and the disadvantages that can already be seen this is likely to take several years.

A1.6 Susanne Sivborg, Director General and President, the Swedish Patent Office

The interview was carried out in Swedish. I have included a translation into English below in sections A1.6.4, A1.6.5 and A1.6.6.[59]

A1.6.1 Europeiska Patent med enhetlig verkan

Man har inte i förslaget uppnått det skydd som var avsett.

Skyddet kommer endast omfatta 25 EU-länder, vilket gör systemet problematiskt.

Trots det enhetliga patentet måste de ändå översättas till olika språk. Även om detta sker maskinellt finns kostnader. Hur detta ska finansieras är i dagsläget ännu oklart. Systemet ska till viss del betala för detta. Exakt hur det ska finansieras är ännu inte helt entydigt.

A1.6.2 European and European Union Patent Court

Domstolslösningen kommer inte att fungera för alla EPO-länder utan det blir en domstolslösning endast för EU.

[59] The translation was carried out by the author of the thesis.

Industrin vill ha ett skydd för sina patent och som det ser ut nu är skyddet undermåligt.

Problemet ligger egentligen hos domstolsförslaget eftersom det är där skyddet för innovationen faktiskt skyddas aktivt.

Det skydd som erbjuds i förslaget kommer att vara dyra, jobbiga och besvärliga.

Nyckelfrågan, var domstolen och underinstanserna ska placeras är ännu oviss.

Hur olika instanser ska fungera är också mycket viktigt och ännu inte beslutat.

Många ministrar inom EU vill ta beslut utan att ha någon fastställd processordning. Detta förslag är många inom industrin emot.

PRV delar industrins uppfattning i dessa frågor.

A1.6.3 Jämförelse

Som förslaget ser ut kommer det finnas tre val för den som ansöker om patent i Europa Europeiska patent, nationellt eller det Enhetliga Patentskyddet.

Sivborg förutspår att det kommer vara stora branschskillnader gällande vilka som sannolikt kommer ansöka Enhetliga Patent, Europeiska patent och nationella patent.

Enhetligt kommer vara mycket branschspecifikt. Vissa industrisektorer kommer säkerligen inte att använda sig av det Enhetliga Patentet.

Det kommer sannolikt få genomslag efter lång tid men inte samma effekt som önskat på grund av att den kvalitet som kan erbjudas är mycket viktig för hur bra det kommer fungera.

Nationella patent kommer säkerligen åtminstone initialt få ett uppsving.

A1.6.4 The Unitary Patent and the translation arrangements

The proposal will not give the desired protection that was initially intended.

The protection will only apply to the 25 EU countries that have joined the scheme, which makes the process still complicated.

Despite a Unitary Patent, translations will still have to be done. Even if this is carried out by computers, there will still be costs. How this is to be financed is still unclear.

The System is said to help pay for this. The details of the financing have not been finally decided or outlined yet.

A1.6.5 The European and European Union Patent Court

The court arrangements will not be operational for all EPO countries; instead it will be a court proposal will only apply for the EU.

The Industry wants protection for their patents and as the draft stands this protection is insufficient.

The problem is rather due to the court proposal as opposed to the patent protection proposal since that is where the protection of the innovation is actually enforced.

The protection offered by the draft agreement will be expensive, tedious and complicated.

The question of the court locations is still unknown and will have a large impact on the proposal as a whole.

How the various bodies of the court organization including the appeal procedure is not decided upon yet.

Many of the ministers in the EU parliament want to take a vote on the EEUPC without having decided on the rules of procedure. A large proportion of the industry oppose this action.

The Swedish Patent Office shares the industry's views in these questions.

A1.6.6 Comparison

As the proposal currently stands there will be three options open to patent applicants in Europe, namely the European patent, national patent and the Unitary Patent.

Sivborg believes there will be big differences between different industry sectors' choice of patent type.

The Unitary Patent will be popular in some industry sectors, whereas some sectors will not be applying for the Unitary Patent.

In due course it is likely that the Unitary Patent will become increasingly popular but initially the effect will not be as desired due to the low quality of protection offered by the Unitary Patent, which is very important for how it will be received by the industry and work in practice.

We will probably see national patent applications experiencing an upswing in the first few years of the Unitary Patent.

A1.7 *Anonymous* External IP Affairs Manager at a major European pharmaceutical company[60]

A1.7.1 The Unitary Patent and the translation arrangements

In the current draft articles 6, 7 and 8 have been included in the EU draft of the agreement. This means that the EUCJ will have jurisdiction to help courts interpret the meaning of these articles. This is a setback to the Unitary Patent since we know that the

[60] The interviewee has chosen to be anonymous for a number of reasons.

EUCJ record on intellectual property is not so good. This will certainly have consequences.

I have learned that some companies find this issue absolutely crucial.

A1.7.2 The European and European Union Patent Court

The main purpose of the court is to simplify enforcement for the Unitary Patent.

The Central Division will affect courts and companies Union wide.

If we win it is indeed very good for us that the decision will be valid in the whole Union. But on the other hand a very valuable asset can be lost as an effect of a single court ruling at a Local Division. This adds importance to the Court issue.

Losing an important patent can easily cause the share to drop by five percent as we have seen in the US.

The Quality of the courts will have to be very high.

There are provisions in the draft that outlines the specialisation of the judges in the Local Divisions. Despite the text in the draft it will be very difficult to fulfil this. The judges are likely to be less specialised.

The Local Divisions will have two judges from the country of the Local Division and one from a different country. These judges are likely to have diverging views on how the hearing should be carried out.

I do not see that the issue with forum shopping will be resolved with the EEUPC since there will still be Local Divisions in several places and they are likely to differ in many ways.

The Central Division will probably be the best court but not all cases will be handled by the Central Division.

Revocation and infringement can be dealt with at the same time by courts but this is not currently the case in all countries.

The opt-out provisions of the draft must be extended so that patent holders are not forced into a system that does not work properly.

The rules of procedure will to some extent by at the discretion of the judges. This will also mean there will be a certain degree of forum shopping.

Discovery is very strong in the U.K. for example and not as strong in other parts of Europe and the location of the Central Division will clearly affect how discovery will be perceived by the EEUPC.

Cross examination I think is a very valuable tool to keep witnesses closer to the truth. This is something that is not permitted in Germany for example. In the Anglo-Sax system this is an important part of the procedure.

The Central Division will have an enormous impact on Europe in this area and therefore the discussions at the moment have become more of a political discussion rather than producing a Unitary Patent system that is fair and works for the whole of Europe.

A1.7.3 Comparison

I think this could be a very very good system eventually but we need a very good system to begin with to get there.

It is objectively equally important that the rights of the patent holder and the defendant are both respected.

As the draft stands at the moment the EEUPC is not good enough.

This will cause companies choosing the national route instead. Some companies havea already began avoiding the European patent system as they fear the EEUPC will get jurisdiction over these patents eventually.

The EUCJ should not apply for European patents.

As it looks today the suggested patent system is not better. Mainly due to articles 6, 7 and 8 of the Unitary Patent agreement, the rules of procedure of the EEUPC, the limited possibility to opt-out and the likely low specialisation in the EEUPC.

Simple changes to the draft could make it acceptable, but without these the draft is not acceptable.

Appendix 2 Epilady, European Patent Office patent EP 0330091 A3[61]

A2.1 Title

Depilatory device.

A2.2 Abstract

A depilatory device comprising a hand-held portable housing (10), motor apparatus (16) disposed in the housing; first and second helical springs (36, 38) arranged to be driven by the motor apparatus (16) in rotational sliding motion relative to skin bearing hair to be removed, the first and second helical springs (36, 38) each including an arcuate hair engaging portion arranged to define a convex side at which the windings are spread apart and a concave side corresponding thereto at which the windings are pressed together, the rotational motion of the helical spring producing continuous motion of the windings from a spread-apart orientation at the convex side to a pressed together orientation at the concave side for engagement and plucking of hair from the skin.

A2.3 The patent claims

1. A depilatory device comprising: a hand-held portable housing; motor means disposed in said housing; first and second helical springs arranged to be driven by said motor means in rotational sliding motion relative to skin bearing hair to be removed, the first and second helical springs each including an arcuate hair engaging portion arranged to define a convex side at which the windings are spread apart and a concave side corresponding thereto at which said windings are pressed together, said rotational motion of said helical spring producing continuous motion of said windings from a spread-apart orientation at said convex side to a pressed together orientation at said concave side for engagement and plucking of hair from the skin.

2. A depilatory device comprising: a hand-held portable housing; motor means disposed in said housing; at least one helical spring arranged to be driven by said motor means in rotational sliding motion relative to skin bearing hair to be removed, said at least one helical spring including an arcuate hair engaging portion arranged to define a convex side at which said windings are spread apart and a concave side corresponding thereto at

[61] http://ip.com/patapp/EP0330091A3

which said windings are pressed together, said rotational motion of said helical spring producing continuous motion of said windings from a spread-apart orientation at said convex side to a pressed together orientation at said concave side for engagement and plucking of hair from the skin; and means for varying the orientation of said arcuate hair engaging portion.

3. A depilatory device according to claim 1 and wherein said first and second helical springs are driven in opposite directions of rotation.

4. A depilatory device according to claim 1 and wherein said first and second helical springs may be arranged such that they lie generally in a spread-apart orientation.

5. A depilatory device according to claim 3 and wherein said first and second helical springs be arranged such that they lie generally in a spread-apart orientation.

6. A depilatory device according to claim 1 and wherein said first and second helical springs may be arranged such that they lie in generally parallel planes.

7. A depilatory device according to claim 3 and wherein said first and second helical springs may be arranged such that they lie in generally parallel planes.

8. A depilatory device according to claim 6 and wherein said first and second helical springs may also be arranged such that they lie generally in a single plane perpendicular to said generally parallel planes.

9. A depilatory device according to claim 8 and wherein said first and second helical springs may also be arranged such that they lie at a selectable orientation between said generally parallel planes and said single plane perpendicular thereto.

10. A depilatory device according to claim 1 and also comprising a stiffening spring associated with each of said first and second helical springs.

11. A depilatory device according to claim 1 and wherein no stiffening spring is associated with either of said first or second helical springs.

12. A depilatory device according to claim 11 and also comprising mounting pins fixed in said housing for rotatable mounting of said first and second helical springs at their respective ends.

13. A depilatory device according to claim 11 and wherein said first and second helical springs are removably mounted in said housing.

14 A depilatory device according to claim 1 and also comprising means for varying said orientations of the arcuate portions of said first and second helical springs.

15. A depilatory device according to claim 2 and wherein said at least one helical spring may be arranged such that it lies at a selectable orientation.

16. A depilatory device according to claim 2 and also comprising a stiffening spring associated with said at least one helical spring.

17. A depilatory device according to claim 2 and wherein no stiffening spring is associated with said at least one helical spring.

18. A depilatory device according to claim 17 and also comprising at least one mouting pin fixed in said housing for rotatable mounting of said at least one helical spring.

19. A depilatory device according to claim 17 and wherein said at least one helical spring is removably mounted in said housing.

Appendix 3 Esomeprazole, European Patent Office patent EP1020461B1[62]

A3.1 Title

Magnesium salt of the (-)-enantiomer of omeprazole[63] and its use.

A3.2 Abstract

The use of an alkaline salt of the (-)-enantiomer of omeprazole for the manufacture of a pharmaceutical preparation having improved pharmacokinetic and metabolic properties, such as improved therapeutic profile when treating gastric acid related diseases.

A3.3 Claims

1. The use of a magnesium salt of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole ((-)-omeprazole) with an optical purity of ≥ 99.8% enantiomeric excess (e.e.) for the manufacture of a medicament for the inhibition of gastric acid secretion.
2. The use as claimed in Claim 1 wherein the salt is crystalline.
3. The use as claimed in Claim 1 or Claim 2 wherein medicament is for the treatment of a gastric acid-related disease and/or a gastrointestinal inflammatory disease.
4. The use as claimed in Claim 3 wherein the disease is a gastric ulcer, a duodenal ulcer, reflux esophagitis or gastritis.
5. The use as claimed in Claim 4 wherein the disease is reflux esophagitis.
6. The use as claimed in Claim 1 or Claim 2 wherein the patient is on NSAID therapy, has a gastrinoma and/or has acute upper gastrointestinal bleeding.
7. The use as claimed in Claim 1 or Claim 2 wherein the medicament is for the treatment of a patient in an intensive care situation and/or is to be used pre- and postoperatively to prevent acid aspiration and stress ulceration.

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[62] Patent application EP89102779.9, http://www.patentlens.net/patentlens/patent/EP_1020461_B1

[63] The (-)-enantiomer of omeprazole is called esomeprazole.

8. The use as claimed in Claim 1 or Claim 2 wherein the medicament is used in the treatment of a Helicobacter infection.
9. A magnesium salt of (-)-5-methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)-methyl]sulfinyl]-1H-benzimidazole ((-)-omeprazole) with an optical purity of ≥ 99.8% enantiomeric excess (e.e.).
10. A salt as claimed in Claim 9 for use in therapy.
11. A salt as claimed in Claim 10 for use in the treatment or prophylaxis of a condition as defined in any one of Claims 3 to 8.
12. A salt as claimed in any one of Claims 9 to 11 which is crystalline.
13. A pharmaceutical composition of a salt as claimed in any one of Claims 9 to 12 together with a pharmaceutically acceptable carrier.