FACULTY OF LAW
Lund University

Karolina Jivebäck Pap

An even application of plausibility?

A legal study of the application of the principle of legal certainty to the plausibility threshold in relation to pharmaceutical patents in European patent law

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Supervisor: Ana Nordberg

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Contents

Summary

The plausibility threshold started, and is still, developing through the case law of the EPO. It is used as a tool against speculative patents, as the claimed technical effect of the invention must be made *plausible*. The plausibility threshold is foremost being used at the EPO in relation to the requirement of an inventive step under Article 56 EPC and the requirement of sufficiency of disclosure under Article 83 EPC, even though it is not mentioned within any of those provisions or anywhere else in the EPC.

In order for the patent system to fulfil its fundamental purpose, namely to properly work as incentives for innovation, it is crucial that the system provides legal certainty for applicants, patent owners and third parties. However, an uneven application of the plausibility threshold could potentially be inconsistent with this fundamental purpose. Therefore the purpose with this essay was to examine and discuss the application of the principle of legal certainty to the plausibility threshold in relation to pharmaceutical patents in European patent law.

For fulfilling the purpose of this essay, plausibility was examined in the pre-grant procedure through the case law of the EPO, as well as post-grant procedure through Swedish and UK case law. In this regard it was concluded that it has been applied unevenly within and between those jurisdictions. Plausibility was moreover examined in relation to Markush type claims as they are broad by their very nature and, thus, risk creating legal uncertainty. On the other hand they are considered as the most precise way of defining chemical compounds, and are important for innovation within the pharmaceutical sector. In this regard it was concluded that the plausibility threshold originate specific issues. Finally it was discussed if there should be a provision on plausibility within the EPC to tackle these uncertainties, with the conclusion that it could be a good solution. Although, only if such a provision could be formulated in an unambiguous way.

Sammanfattning

Sannolikhetskriteriet (plausibility) började och håller fortfarande på att utvecklas genom EPO:s rättspraxis. Det används som ett verktyg mot spekulativa patent, eftersom den påstådda tekniska effekten av en uppfinning måste göras sannolik. Kriteriet används främst vid EPO i förhållande till kravet på uppfinningshöjd enligt artikel 56 EPC och kravet på tillräcklig information för att fackmannen ska kunna utföra uppfinningen enligt artikel 83 EPC, även om det inte nämns i någon av dessa bestämmelser eller någon annanstans i konventionen.

För att patentsystemet ska kunna uppfylla sitt grundläggande syfte, nämligen att fungera som incitament för innovation, är det avgörande att systemet utger rättssäkerhet för sökande, rättighetsinnehavare och tredje man. En ojämn tillämpning av sannolikhetskriteriet kan dock vara oförenlig med det grundläggande syftet. Syftet med denna uppsats var därför att undersöka och diskutera tillämpningen av principen om rättssäkerhet på sannolikhetskriteriet för läkemedelspatent inom den europeiska patenträtten.

För att uppfylla syftet med denna uppsats undersöktes sannolikhetskriteriet i förhållande till förfarandet innan beviljande av patent genom EPO:s rättspraxis, liksom förfarandet efter beviljande genom svensk och brittisk rättspraxis. I detta avseende drogs slutsatsen att kriteriet har tillämpats ojämnt inom och mellan dessa jurisdiktioner. Det undersöktes dessutom i förhållande till patentkrav baserade på en s.k. Markushformel, eftersom dessa till sin natur är väldigt breda och därmed riskerar att skapa rättsosäkerhet. Å andra sidan betraktas de som det mest exakta sättet att definiera kemiska föreningar och är således viktiga inom läkemedelssektorn. I detta avseende drogs slutsatsen att sannolikhetskriteriet orsakar specifika problem. Slutligen diskuterades det om, och kom fram till att, det borde finnas en bestämmelse angående sannolikhetskriteriet inom EPC för att ta itu med dessa osäkerheter. Dock, endast om denna kan formuleras entydigt.

Preface

Det var aldrig en självklarhet för mig att jag skulle studera juridik. Däremot var jag helt säker på att jag ville studera i Lund (utan att ha varit här tidigare), och tänk så rätt allting blev. Nu, sex år efter den där första, nervösa, dagen på Jurren är jag så otroligt tacksam över att det blev både juridik och Lund.

Jag vill såklart börja med att tacka alla mina fina vänner som gjort de här åren till de bästa. Ni har fått Lund att kännas som hemma!

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A big thank you to my supervisor Ana Nordberg. If it was not for your interesting course in European Patent law I never would have thought of writing about this topic. Your constructive and detailed feedback has been invaluable for the writing of this thesis.

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Lund, maj 2021
Karolina Jivebäck Pap

Abbreviations

AIPPI	International Association for the Protection of Intellectual Property
BoA	Boards of Appeal
CML	Chronic myelogenous leukaemia
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
MA	Marketing authorisation
MS	Multiple sclerosis
PCT	Patent Cooperation Treaty
PTKs	Protein tyrosine kinases
SPC	Supplementary Protection Certificate
TBA	Technical Board of Appeal
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Office
WTO	World Trade Organisation

1 Introduction

1.1 Background

The plausibility threshold emerged, and is still developing, through the case law of the European Patent Office ("EPO"). It is used as a tool against speculative patents, as it is applied as a requirement in relation to technical contribution of the invention. Thus, the claimed technical effect should be made *plausible*.[1] However, one might question how much legal certainty it really provides when being applied by the EPO in the pre-grant procedure, or national courts when they rely on the EPO case law in the post-grant procedure.[2] The legal certainty issue can be expected to arise in particular in relation to patents and patent applications which by their very nature have a wide scope, such as pharmaceutical patents in the form of Markush type claims.[3]

For the purpose of this essay, the principle of legal certainty has to be defined. Legal certainty is one of the elements falling under the concept of rule of law. What is meant by "rule of law" or "the supremacy of the law" is that everyone is subject to the law, no one is above it.[4] Mullally display the broadness of the principle of legal certainty by stating that it has many different aspects and causes. The author uses examples such as uncertainties when there are no rules existing yet within a certain area of law or when there are rules existing, but their contents are difficult to determine. It might furthermore be unclear how a rule will be interpreted by the courts.[5]

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[1] Andrew J K Wells 'Technical contribution and plausibility: the approach of the European Patent Office and the courts of England and Wales' (2019) Vol. 14 No. 10 JIPLP 784, 784, 787.
[2] See chapter 3 and 5.
[3] A single claim that defines several (chemical or non-chemical) alternatives, see chapter 4.
[4] Rafael Leal-Arcas, 'Essential Elements of the Rule of Law Concept in the EU' (2014) Queen Mary University of London School of Law Legal Studies Research Paper No. 180/2014, 1 <https://ssrn.com/abstract=2483749> accessed 13 April 2021.
[5] Kelly C. Mullally 'Legal (Un)Certainty, Legal Process, and Patent Law' (2010) 43 Loy. L.A. L. Rev. 1109, 1120.

As argued by Ann, patents need to contain at least some amount of legal certainty. If not, their role as incentives for innovation is undermined. This, as it can be costly to invest in innovation and the inventors would, without at least a minimum amount of legal certainty, not be able to fully rely on the possibility to protect their inventions.[6] Mullally, similarly to Ann but from an USA law perspective, problematises the relationship between legal certainty and patents. Stating that the fundamental goal of the patent system - to work as incentives for innovation - risks being undermined by legal uncertainties.[7]

The principle of legal certainty is found in the European Patent Convention[8] ("EPC"), namely within its Article 69, which concern the extent of protection conferred by a patent. The principle is not directly expressed in the article, but in the Protocol on its interpretation. This Protocol, thus, states that Article 69 should not be interpreted as meaning that the protection conferred by a patent granted under the EPC is to be defined strictly by the literal wording of the claims, drawings and the patent description. Instead, it should be interpreted as meaning that a balance must be struck between fair protection to the patent owner as well as legal certainty for any third parties.[9] Within this essay, legal certainty for third parties will be explored, but also legal certainty for the applicants within the pre-grant procedure as well as legal certainty for patent owners in the post-grant procedure when the plausibility threshold is applied.

[6] Christoph Ann 'Patent invalidation and legal certainty – What can patent holders expect?' (2016) Technische Universität München (TUM) - TUM School of Management, 12 <https://ssrn.com/abstract=2804992> accessed 13 April 2021.
[7] Kelly C. Mullally (n 5) 1112-1113.
[8] Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000. See section 2.1.2 for a more detailed description of the EPC and the European Patent Organisation.
[9] Article 1 in the Protocol on the Interpretation of Article 69 of 5 October 1973 as revised by the Act revising the EPC of 29 November 2000.

1.2 Purpose

The purpose of this essay is to examine and discuss the application of the principle of legal certainty to the plausibility threshold, when the threshold is used in relation to pharmaceutical patents in European patent law, as it can be questioned whether they are really compatible with one another. It is namely crucial for the patent system to provide legal certainty for the applicants, patent owners and third parties in order to maintain the fundamental goal of the system; to work as an incentive for innovation.[10] In order to fulfil this purpose, this essay will examine the questions stated in the section below.

1.3 Research questions

- Has the plausibility threshold been applied evenly throughout the EPO case law?
- Do Markush type claims originate specific issues regarding the plausibility threshold?
- Has the plausibility threshold been applied evenly within and between different national jurisdictions?
- Is there a need for a specific legal provision on plausibility within the EPC to harmonise and tackle uncertainties regarding the application of the plausibility threshold?

1.4 Delimitations

Patent law is a broad area of law, why plausibility in relation to pharmaceutical patents was chosen for the purpose of this essay. This choice is moreover motivated by the fact that the primary EPO case law on the topic of plausibility specifically concern pharmaceutical patents, as is displayed in chapter 3.

[10] See section 1.1.

At the EPO level, i.e. in the pre-grant procedure, plausibility has foremost been applied in relation to inventive step in Article 56 EPC as well as sufficiency of disclosure in Article 83 EPC. This can be compared with for example UK patent law where the application of the plausibility threshold has been applied extensively, e.g. in relation to novelty as well.[11] However, when examining UK case law in chapter 5 it will solely be in relation to inventive step and sufficiency, in order to ensure consistency throughout the essay as well as a solid basis for the comparative analysis in chapter 5 and 6.

The plausibility threshold was moreover problematised against one of the normal ways of creating compound claims, namely through Markush type claims. This, as many of the plausibility cases examined concerned applications based on this type of claims, and therefore the question arose if they originate any specific issues in that regard. Markush type claims, for example, interestingly contain so called non-working embodiments[12] and it can be questioned if and how these are compatible with the plausibility threshold as it has developed through the case law of the EPO.

In order to get a wider perspective on how the plausibility threshold has been applied in Europe, it is necessary to examine not only pre-grant decisions at the EPO, but also post-grant procedure as well. It was thus necessary to conduct a case law analysis on how different national jurisdictions have applied the plausibility threshold. In this regard Sweden and United Kingdom were the chosen jurisdictions. Swedish case law was chosen due to its natural relevance and the UK for being a major patent jurisdiction in terms of volume of case law on plausibility[13].

[11] See in this regard e.g. Miquel Montañá 'What's the legal basis for plausibility?' (*Kluwer Patent Blog*, 28 April 2017) <http://patentblog.kluweriplaw.com/2017/04/28/whats-the-legal-basis-for-plausibility/> accessed 11 March 2021.
[12] See section 4.1.2.
[13] See section 5.1.

1.5 Methodology

1.5.1 Legal dogmatic method

Within this essay, a legal dogmatic method is used. This method comprises the analysis of the different elements of the legal sources, in order to find out how the law should be considered in specific situations. It is based on the law and case law, combined with for example legal doctrine on the topic. The level of independent value the legal doctrine has is not completely clear and there are different opinions among the scholars. Kleineman is however of the opinion that it is valuable as it is not as fragmentary as the other legal sources. It is moreover importantly used to point out inconsistencies in the case law of a court.[14] Thus, the legal dogmatic method can in short be characterised as a reconstruction of the legal system.[15]

Olsen points out the view within the legal doctrine that the traditional legal dogmatic method is only concerned with *de lege lata* (the law as it is) and not historical aspects (what the law was) or *de lege ferenda* (what the law should be). This can be problematic in dynamic legal areas. The legal dogmatic method can moreover be problematic to utilise in situations where legal norms from various legal traditions are supposed to be combined, as different legal systems might put different values in a legal source.[16] Thus, to only use the traditional legal dogmatic method in this essay would not be sufficient as for example the decisions of the EPO are not directly binding on the states that have ratified the EPC – but they follow them anyways[17].

[14] Jan Kleineman, 'Rättsdogmatisk metod' in Maria Nääv & Mauro Zamboni (eds), *Juridisk Metodlära* (2nd edn, Studentlitteratur AB 2018) 26, 33-35.
[15] Nils Jareborg, 'Rättsdogmatik som rättsvetenskap' (2004) SvJT 1, 4.
[16] Lena Olsen, 'Rättsvetenskapliga perspektiv' (2004) SvJT 105, 116-117.
[17] See chapter 5.

Moreover, the Guidelines for Examination in the European Patent Office ("the EPO Guidelines" or "the Guidelines")[18] are important for the interpretation of the European patent system. According to Olsen, however, a traditional legal dogmatic method only place value in authoritative sources.[19] In this regard, it is important though to keep in mind that what qualifies as an authoritative source might depend on the legal jurisdiction. One should, thus, be careful in assuming that there is a universal definition of law, as imposing the own legal culture on another one risk obscuring rather than clarifying it.[20] Since the EPO is not a party to the Vienna Convention on the Law of Treaties[21] ("the Vienna Convention"), it is not obliged to apply its provisions. However, the principles of interpretation in Article 31 and Article 32 of the Vienna Convention are still applied when the EPC is being interpreted. The Boards of Appeal also use other sources of international law, like the Agreement on Trade-Related Aspects of Intellectual Property Rights[22] ("TRIPS"), in their decisions as guidance.[23]

As a traditional legal dogmatic method is not sufficient for this essay, a critical/constructive legal dogmatic method is furthermore used. Lambertz divides the constructive legal dogmatic method into two categories. One concerning constructively researching and analysing the law as it is within a specific legal system (*de lege lata*) and one concerning constructively researching and analysing a legal system and give recommendations regarding how it should be changed (*de lege ferenda*).[24] The first three research questions of this essay falls under the first category, as they display

[18] See section 2.1.2 where they are being defined.
[19] Lena Olsen (n 16) 118. See chapter 2 and also compare to the opinion of Kleineman above.
[20] Geoffrey Samuel, *An Introduction to Comparative Law Theory and Method* (Hart Publishing 2014) 9.
[21] Vienna Convention on the Law of Treaties (done at Vienna on 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331.
[22] Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017), Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.
[23] Frédéric Bostedt, Sabine Demangue, Barbara Dobrucki, Ian Eveleigh, Helen Fineron, Filipe Fischmann, Annemarie Grabrucker, Jérôme Serre (eds), *Case Law of the Boards of Appeal* (9th edn, the European Patent Office 2019) III.H.1 781.
[24] Göran Lambertz, 'Nyttig och onyttig rättsvetenskap' (2002) SvJT 261, 265.

and analyse the legal system as it is. The last research question falls under the second category, as it concerns the possible need for change, and a suggestion regarding how it should be done.

For a critical legal dogmatic method, legal doctrine is crucial. The legal doctrine is used to critically analyse the solution to how the law should be considered in specific situations, by for example exploring its consequences. Thus, the doctrine is importantly used to criticise the legal situation, which contributes to the future development of the law.[25] Because of the importance of using legal doctrine to critically analyse the other legal sources it will be widely used as a basis for analysis within this essay.

1.5.2 Comparative legal method

This essay will moreover, when exploring the UK and Swedish case law on the application of plausibility as well as comparing it to the case law of the EPO, use a comparative legal method. As it sounds, the comparative method comprises the comparison of similarities and dissimilarities of two or more legal systems. This method is used to explore how different cultures regulate their society. Furthermore, when harmonising different legal systems, the comparative method is very valuable as it can be used to find a common ground or basis within those legal systems.[26] However, Legrand argues that the comparative legal method should be concerned with measuring differences, not presuming similarities and therefore, it is crucial not to solely focus on identifying similarities when making a comparison, as they risk being superficial.[27]

As stated by Samuel, the comparative legal method cannot be completely separated from other legal methods. Moreover, with a reference to the textbook of Zweigert and Kötz, Samuel argues that there are certain

[25] Jan Kleineman (n 14) 35-36.
[26] Filippo Valguarnera, 'Komparativ juridisk metod' in Maria Nääv & Mauro Zamboni (eds), *Juridisk Metodlära* (2nd edn, Studentlitteratur AB 2018) 143-145.
[27] Geoffrey Samuel (n 20) 54.

questions existing regarding how the comparative method should be approached. Should one, for example (as problematised in the paragraph above), assume similarity of different legal systems, or on the contrary, dissimilarity? Another crucial question arising is: what is really the purpose behind the comparison? It is furthermore important to reflect on the concept of "law" in comparative law as it might be viewed differently in different legal cultures.[28]

These questions are of course crucial to keep in mind when analysing and comparing the case law of the UK and Sweden. The common law system of the UK can be argued to be very different to the civil law system of Sweden. Legrand expressed such an opinion, stating that there are considerable cultural differences between civil law and common law. Bell on the other hand has disputed this approach, arguing that the differences are exaggerated.[29] No matter what approach one might have, it is important to keep in mind that both the UK Patents Act (the Patents Act 1977[30]) and the Swedish Patents Act (Patentlagen[31]) are adjusted after the EPC[32]. As will be displayed in chapter 5, both countries have closely followed the case law of the EPO. However, the varying results of their judgments could perhaps be traced back to cultural differences between the two.

There are also differences between making a macro or micro comparison. As mentioned by Samuel, however, this is quite a general and simplistic division. It is nevertheless, according to the author, touching upon important questions and is still useful. Based on this kind of division, when making a comparison between two legal systems one is making that comparison on a macro-level. If one is, on the other hand, making a comparison between specific areas of law within two legal systems one is making a comparison on a micro-level.[33] In this essay, the comparison can therefore be said to be

[28] Geoffrey Samuel (n 20) 4, 9.
[29] ibid 51.
[30] The Patents Act 1977.
[31] Patentlag (1967:837).
[32] See more detail of the relevant provisions under chapter 5.
[33] Geoffrey Samuel (n 20) 50.

made on a micro-level as there is only a specific area of law that is being compared (patent law – and more specifically plausibility) when looking at the UK and Swedish case law in chapter 5 as well as the comparison with the case law of the EPO throughout the essay.

1.5.3 Teleological interpretation

Within this essay, a teleological interpretation is furthermore used in order to establish the laws *ratio legis* (the reason behind the law).[34] What is meant with this, is that an unclear wording of the law can be clarified by interpreting it in relation to the reason behind it.[35] This way of interpreting the law can either be done objectively or subjectively. An objective interpretation is solely connected to the objective circumstances connected to the law, while the subjective interpretation is connected to the purpose behind, and considerations in relation to, why the law was created in the first place.[36]

Rosén argues that from a legal certainty perspective, the subjective teleological interpretation is the better one to use as it has not been completely clarified, within the legal doctrine, which objective circumstances should be used as a basis for the objective interpretation.[37] However, it should be problematised in relation to the subjective interpretation, as expressed by Hult, that sometimes there might be several purposes behind the creation of a law. Then the problem lies in deciding which purpose should be used for the interpretation.[38] While being aware of this potential problem, this essay uses a subjective teleological interpretation, as the historical aspect and purpose behind the creation of the European patent system is important for understanding and establishing its reason, in relation to plausibility.

[34] Johan Rosén 'De svenska lagförarbetenas vara eller inte vara som rättskälla – effekter av Sveriges anslutning till den Europeiska unionen' (1996) SvJT 244, 247.
[35] Phillips Hult 'Lagens bokstav och lagens andemening' (1952) SvJT 579, 588.
[36] Johan Rosén (n 34) 247.
[37] ibid.
[38] Phillips Hult (n 35) 591.

1.6 Material and current research

Within this essay quite a large variation of primary and secondary sources have been used; provisions, case law, guidelines, books, articles, legal blogs and webpages. The more basic understanding of the patent system and pharmaceutical patents in chapter 2 is mostly based on legal doctrine in the form of different books on those topics. When using these books it was important to bear in mind that some of them, for example Domeij's *Pharmaceutical Patents in Europe*[39], are a bit older. They were nevertheless appropriate to use, in my opinion, due to their relevant information and discussions. However, it was important to compare the information within them with the current EPO Guidelines or newer books (if there were any) in order to ensure that the information used is still up to date. Domeij's *Pharmaceutical Patents in Europe* was also the most predominant legal doctrine found on Markush type claims and the issues connected to them. Although, for a more varied discussion on those issues, it would have been helpful to have a larger variation of sources.

Regarding the legal doctrine on plausibility, it should be noted that due to lack of traditional sources - i.e. academic studies, non peer-reviewed materials were used for inspiration, mostly of UK practitioners. Thus, two aspects must be mentioned in that regard. Firstly, that the view of a practitioner on a legal topic might vary to the one of a legal scholar. This absence of academic studies could potentially be explained by the fact that the issues connected to the application of plausibility mostly affect legal practitioners. The second aspect that should be mentioned is that since most articles are of UK practitioners, it is inevitable affected by UK legal traditions and perspectives[40]. Moreover, it is unfortunate for the comparison of the Swedish and UK case law that there are no articles on plausibility from Swedish scholars or practitioners. This can however be used as

[39] Bengt Domeij, *Pharmaceutical Patents in Europe* (Nordstedts Juridik AB 2000).
[40] However, it is debated how big the cultural differences really are, see section 1.5.2 above.

evidence of the varying approaches to the concept of plausibility between those legal jurisdictions, as will be explored in chapter 5.

As for the EPO case law used in chapter 3, my aim was to find the most predominant cases as well as newer ones that had been commented on within the legal doctrine due to their application of the plausibility threshold. The UK case law used in chapter 5, was found through the legal doctrine, where my ambition also was to find and use the most predominant cases. Since the case law on plausibility in the UK is highly developed, it was quite difficult to find the most important cases. Especially due to my unfamiliarity with this legal jurisdiction. Finding the Swedish case law in chapter 5 was difficult for the complete opposite reason, as there was not much case law found on plausibility at all, and only from the lower courts.

1.7 Disposition

This essay is divided into seven chapters. After the introduction, the second chapter sets out to create a basic understanding of the patent system in Europe as well as a short introduction to pharmaceutical patents. The third chapter concerns the first question posed, namely how the plausibility threshold has been applied in the EPO case law. The fourth chapter concerns the very specific second question; whether the Markush type claims originate any specific issues regarding the application of the plausibility threshold. The fifth chapter concerns the third question posed, which is how the plausibility threshold has been applied by different national jurisdictions. The final discussion in the sixth chapter is focusing on the last question posed, namely if there is a need for a specific provision within the EPC to clarify the application of the plausibility threshold. This chapter is moreover bringing the previous analyses together, to fulfil the overall purpose of the essay. This is finally followed by a conclusion in the seventh chapter.

2 The European patent system

2.1 History and purpose of the patent system

2.1.1 Historical background

"Patent" as a term is short for "letters patent", which was historically issued by the English Crown. These letter patents either concerned a referral of a right, a privilege or constituted another way of demonstrating the will of the Crown. However, the idea of granting patents for inventions can be traced all the way back to Greece in 500 BCE, where exclusive manufacturing or other kind of privileges was conferred to people who invented new products or processes. This way of providing incentives for innovations was also adopted by the Romans who, for example, used exemption from obligatory military service as such an incentive. Moreover, in the 15th century the first general patent statute came into force in Venice.[41]

Moving forward a bit in history, in 1623 the British Parliament introduced the Statute of Monopolies. France followed England's example and in 1791 they created their first general patent legislation. In the middle of the 19th century many other European countries followed as well, even though some national systems created were very different from one another. However, these kind of systems were not free from controversy. In many European countries supporters of free trade thought the domestic patent laws would damage innovation and industry and therefore sought the abolition of them. Despite all this, the debate ended by the end of 1870's with those advocating for patents as winners and the first international patent treaty, the

[41] Justine Pila, Paul Torremans, *European Intellectual Property Law* (2nd edn, Oxford University Press 2019) 14-15, 100.

Paris Convention for the Protection of Industrial Property[42], was concluded in 1883.[43]

In more recent history, several international patent collaborations have been created in order to simplify the patent application process. The Patent Cooperation Treaty[44] ("PCT") is one of them, which came into force in 1978. In order to simplify the application process, the applicant only have to submit one international patent application to a national authority or a competent international organisation, like the EPO[45] or the World Intellectual Property Office ("WIPO").[46]

Also important to mention is TRIPS that came into force in 1995. All parties to the WTO are bound by this agreement[47], which makes it of relevance for the purpose of this essay since Sweden and the UK are such parties[48]. Within this agreement are important provisions on for example the patentable subject matter (Article 27), the exclusive rights a patent confers (Article 28), and the limitations to it (Article 30).[49] Thus, based on this historical background, my position is that it is clear how the fundamental idea behind the patent system, to provide incentives for innovation, can be seen throughout the history of the patent, having an almost universal character. It is also clear that the development of the patent system, and patents as such, has not been free from controversy.

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[42] Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967, and as amended on September 28, 1979.
[43] Justine Pila, Paul Torremans (n 41) 16-17.
[44] Patent Cooperation Treaty, Done at Washington on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984, and on October 3, 2001.
[45] See section 2.1.2 for more information about this organisation.
[46] Bengt G. Nilsson, Catarina Holtz, *Patentlagen – en kommentar och en jämförelse med EPC och PCT* (Jure Förlag AB 2012) 16.
[47] ibid 21.
[48] See 'Sweden and the WTO' (*WTO*) <www.wto.org/english/thewto_e/countries_e/sweden_e.htm> and 'United Kingdom and the WTO' (*WTO*) <www.wto.org/english/thewto_e/countries_e/united_kingdom_e.htm> both accessed 24 February 2021.
[49] Bengt G. Nilsson, Catarina Holtz (n 46) 22.

2.1.2 The European Patent Organisation

In Europe we now have the European Patent Organisation, which is based on the EPC, a convention that was ratified in Munich in 1973.[50] It, thereafter, came into force in 1977. The European Patent Organisation comprises the EPO and the Administrative Council.[51] In Article 4(3) of the EPC the role of the Organisation is established, which is to grant European patents. In this Article it is further stated that the EPO is carrying out the task of granting patents while the Administrative Council is acting as supervisor.[52] The purpose of creating the European patent system was to centralise and make affordable the granting of patents within Europe.[53] At the end of the 1900's the work of renewing the EPC started in the form of EPC 2000, which came into force on the 13 of December 2007.[54]

The EPO thus functions as the single examining division of patent applications under the EPC, resulting, where appropriate, in the grant of a European patent in all the contracting states the applicant has designated. The patent rights are therefore still territorial.[55] Moreover, in relation to the nature of patents, one important aspect is that patents do not confer any positive rights on the patent owner. Only the right to keep others from practicing the invention.[56] The EPC regulates the application, granting and opposition procedures of the European patents.[57] However, post-grant procedures, like infringement procedures or procedures concerning the validity of a patent are delt with under national procedural law.[58] The EPO

[50] Nicolai Lindgreen, Jens Schovsbo, Jesper Thorsen, *Patentloven med kommentarer* (Jurist- og Økonomforbundets Forlag 2012) 64-65.
[51] Gerald Paterson, *The European Patent System – The Law and Practice of the European Patent Convention* (2nd edn, Sweet & Maxwell 2001) 3-4.
[52] Article 4(3), European Patent Convention.
[53] Nicolai Lindgreen, Jens Schovsbo, Jesper Thorsen (n 50) 65.
[54] Bengt G. Nilsson, Catarina Holtz (n 46) 19.
[55] Richard Hacon, Jochen Pagenberg, *Concise European Patent Law* (2nd edn, Kluwer Law International 2008) 1.
[56] Philip W. Grubb, Peter R. Thomsen *Patents for Chemicals, Pharmaceuticals, and Biotechnology – Fundamentals of Global Law, Practice, and Strategy* (5th edn, Oxford University Press 2010) 4.
[57] Richard Hacon, Jochen Pagenberg (n 55) 1.
[58] Bengt G. Nilsson, Catarina Holtz (n 46) 19.

cannot provide binding views on those matters. This can result in different national approaches to the concept of the validity of a patent or the scope of the monopoly afforded by a European patent claim.[59]

After the ratification of the EPC most of the contracting states have modified their national patent legislation in order to comply with it. The UK can be taken as an example in that regard. They changed their national patent legislation particularly in order to give effect to the EPC, through the Patents Act 1977 which came into force in 1978. The influence of different national patent laws can also be found within the EPC.[60]

Important to mention are also the EPO Guidelines. The Guidelines have been in force since 1978, but are continuously being amended. In the beginning the EPO Guidelines were the only information on how the provisions within the EPC should be interpreted, and were therefore very important in explaining the practical working of the European patent system. Also at present time, the departments of first instance at the EPO can be expected to follow the Guidelines, whenever they are applicable to the case they have at hand. The EPO Guidelines can get amended based on decisions of the Boards of Appeal ("BoA" or "the Board") or the practical experience of those first instance departments. They can also change if any provisions of the EPC are being amended.[61] If a decision of a BoA is not in line with the Guidelines, they must state why this is the case.[62]

After a patent has been granted, any third party have the possibility to, within nine months from the publication of the grant, oppose that patent.[63] An opposition is made before the opposition division at the EPO, and this might lead to the patent being amended or revoked. If an applicant is unhappy with this, they can furthermore appeal the decision of the

[59] Richard Hacon, Jochen Pagenberg (n 55) 1-2.
[60] Gerald Paterson (n 51) 3.
[61] ibid 7.
[62] Article 20, Rules of Procedure of the Boards of Appeal, version applicable as from 1 January 2020.
[63] Article 99, European Patent Convention.

opposition division to the BoA.[64] According to Paterson, the decisions of a BoA are the most important tools for interpreting the EPC. They are, just like the EPO Guidelines, normally followed by the departments of first instance even when they are not obliged to do so.[65] It is only the department of first instance whose case was appealed and remitted to it that is bound by the decision of the BoA.[66] The BoA comprises the Technical Boards of Appeal ("TBA"), the Legal Board of Appeal, the Disciplinary Board of Appeal and The Enlarged Board of Appeal ("the Enlarged Board").[67]

If there is a question of fundamental importance arising or there is a need for uniform application of the law, a BoA shall, either of its own motion or of the request of one of the parties, refer a question to the Enlarged Board. The decision of the Enlarged Board is binding on that referring Board when it comes to that specific appeal. Moreover, if two Boards have given different decisions on the same legal topic the President of the EPO can decide to refer that question of law to the Enlarged Board for guidance.[68]

2.1.3 Unitary Patent

The above mentioned territorial restrictions of patents combined with the absence of a European Patent Tribunal, have resulted in a long lasting effort to try to create an unitary patent in order to harmonise this area of law.[69] The EPC is not a part of the EU system, and even though all EU Member States are a part of the EPO, there are other countries outside the EU that are as well, for example Norway and Turkey. There is therefore not existing any "EU patent" or "EU patent cooperation". The proposed unitary patent system would however be an EU system, and thus comprises the grant of a patent that would get effect in all EU countries that have decided to be a part

[64] Richard Hacon, Jochen Pagenberg (n 55) 20.
[65] Gerald Paterson (n 51) 9.
[66] Frédéric Bostedt, Sabine Demangue, Barbara Dobrucki, Ian Eveleigh, Helen Fineron, Filipe Fischmann, Annemarie Grabrucker, Jérôme Serre (n 23) V.A.8. 1293.
[67] 'About the Boards of Appeal' (*EPO*) <www.epo.org/law-practice/case-law-appeals/about-the-boards-of-appeal.html> accessed 18 March 2021.
[68] Article 112, European Patent Convention.
[69] Justine Pila, Paul Torremans (n 41) 99.

of this kind of enhanced cooperation. This cooperation would not automatically include all EU countries, and would not be open for non-EU countries. It would, furthermore, still be the EPO granting those patents.[70]

2.1.4 Justifications for patents

Above, the historical background, present procedure for the grant of patents and future plans for a unitary patent have been presented. But the justifications for the entire system must, at least shortly, be explained as well for a deeper understanding of the system as such and the critics to it as, of course, no theory is free from criticism. Perhaps even more so due to the controverses that have been surrounding the patent system throughout its history, as previously displayed[71].

There are different theoretical accounts for the justification of patents, both legal and economic ones. Instrumentalists sees the patent system as an instrument of the state, and justifies it based on that. For instrumentalists, patents are used for incentivising desirable behaviour as well as disincentivising undesirable behaviour. The grant of a patent is, based on this widely supported theory, considered incentivising investments in that invention, which is furthermore regarded as commercially beneficial for the society.[72]

One can however question the instrumentalist theory on some accounts. Firstly, are patents really providing the relevant incentives? Secondly, does the society really benefit from these incentives or the patent rights as such? Based on a contractarian model, the patent is considered as a contract between the patent owner and the society. The patent owner agrees to disclose the invention in exchange for the grant of that patent; which

[70] Nicolai Lindgreen, Jens Schovsbo, Jesper Thorsen (n 50) 62, 64, 66.
[71] See section 2.1.1.
[72] Justine Pila, Paul Torremans (n 41) 85-86.

includes the society agreeing on not performing the invention during a limited time period.[73]

UK economists such as Smith, Bentham and Mill were all endorsing the use of patents as a reward/compensation for inventions in the form of a monopoly. This theory is based on the idea that an inventor should receive proportionate compensation for the benefits they bring to the society and a temporary exclusive monopoly in the form of a patent right is, thus, regarded as the best way of providing such compensation. Opponents to this theory argue that inventions are the results of much more than just the idea of one individual genius and, moreover, that there is no need to reward the inventor as the invention is primarily the result of luck.[74]

A theory closely connected to the one in the paragraph above is the one stating that the monopoly profits creates incentives for innovation. Economists such as Lyon, Ravenshear and Wieser were all supporting this theory. Patents are, based on this theory, justified by the fact that investments in innovation are risky and can only be accepted if the benefits for it have the potential to substantially exceed the risk taken. Taussig have, however, opposed this theory, stating that monetary reward is not a necessity for all people.[75]

2.2 Pharmaceutical patents

Pharmaceutical patents often concern complex chemical compounds. In order to get a wide scope of protection for an invention it is beneficial to formulate many different categories of claims within the same patent application. There are different kind of claims, for example product or process claims and they can all be combined within the same application. Thus, if for example a product claim would not be considered to be novel or

[73] Justine Pila, Paul Torremans (n 41) 85-86, 101.
[74] Adam Karbowski, Jacek Prokop 'Controversy over the economic justifications for patent protection'(2013) 5 Procedia Economics and Finance 393, 395.
[75] ibid.

lacking an inventive step, the application could be revised to only contain the other type of claims. From a legal certainty perspective, it is important that the patent claims are clear. Both for the sake of the patent owner and the competitors, in order for them to know what scope the granted patent will have.[76]

Naturally, for commercial reasons a patent owner strives for a granted patent with a broad scope, as it corresponds to the economic value of the patent. But as mentioned in the paragraph above, from a legal certainty perspective, the claims must still be drafted as precisely as possible as they define a monopoly. Any uncertainties risk resulting in negotiations or court proceedings between the patent owner and its competitors. However, as established by the Board in T 238/88[77], broad claims cannot be equalised to lack of clarity. In this case the chemical term "alkyl", even though it covered an unlimited amount of chemical structures, was considered to be unambiguous to a person skilled in the art. This, according to the Board, also apply to certain other common chemical terms.[78]

2.2.1 Article 53(c) EPC

Diagnostic, surgical and therapeutic methods are, under certain conditions, excepted from patentability under Article 53(c) EPC. In these cases, ethical aspects are heavily influencing the way the patents are regulated, as there is a connection to the public health.[79] Within Article 53(c) EPC it is, however, clearly stated that products, specifically substances or compositions, that are used within these methods are *not* excepted from patentability. Pharmaceutical compositions can furthermore be divided into three different categories: (1) galenic forms (e.g. a new type of tablet, with a specific rate of drug release when swallowed) or new drug delivery systems, (2) a new

[76] Åsa Andersson, Katarina Söderberg 'Patentkravsformulering' in Marianne Levin, Hanna Nilsson, *Läkemedel & Immaterialrätt m.m.* (Jure Förlag AB 2008) 19-20, 23.
[77] T 238/88 *Crown ether* OJ EPO 1992, 709.
[78] Bengt Domeij (n 39) 63, 65.
[79] Linnea Hedström, Hanna Nilsson 'Gränserna till det inte patenterbara området – om undantaget för diagnostiska, kirurgiska och terapeutiska metoder' in Marianne Levin, Hanna Nilsson, *Läkemedel & Immaterialrätt m.m.* (Jure Förlag AB 2008) 35-36.

combination of preparations which comprises two or more active pharmaceutical ingredients that are already known or (3) a composition of a conventional pharmaceutical carrier or excipient together with a compound that has not been used as a drug previously.[80]

Perhaps the above mentioned pharmaceutical definitions are not that clear, and therefore, in this paragraph, follows some explanations. Firstly, a pharmaceutical carrier or drug carrier is used to transport the effective agent to a certain part of the body or to protect it from certain conditions in different parts of the body.[81] Secondly, a pharmaceutical excipient is something other than the active substance within a dosage form, either used in a medicinal product or used in the manufacturing of that product. Pharmaceutical excipients can fulfil different purposes. They can for example be used as antioxidants in order to protect the pharmacological dosage form from oxidating.[82]

2.2.2 Compound claims

Compounds containing therapeutic effects can be defined in three different ways when constructing the claims. These can either be used separately or combined with one another. They are: (1) product-by-process claims, (2) structural formulas and (3) parameters relating to the compounds. Markush type claims[83] are structural formulas. The other two alternatives will now be described shortly. Product-by-process claims are normally used in relation to e.g. naturally occurring chemical compounds, macromolecules and catalysts which are defined by the way they are manufactured. This, as they can be particularly susceptible to structural variations, which is making it difficult for them to be described by their structure in an unambiguous way.

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[80] Philip W. Grubb, Peter R. Thomsen (n 56) 251, 257.
[81] Se-Kwon Kim, Faith Karadeniz 'Biological Importance and Applications of Squalene and Squalane' in Se-Kwon Kim (eds), *Advances in Food and Nutrition Research* (vol. 65 Elsevier Science & Technology 2012) 229.
[82] Pascal Furrer 'The central role of excipients in drug formulation' (2013) 2 EPR <www.europeanpharmaceuticalreview.com/article/18434/the-central-role-of-excipients-in-drug-formulation-2/> accessed 12 March 2021.
[83] See section 4.1.

This type of claims are, however, at risk of creating more uncertainties than structural formulas, as it is rare for these kind of chemical reactions to follow one path.[84]

When it comes to parameters in the claims it refers to the characteristic aspects of a product; the function of a chemical structure. This could for example be the melting point or electric resistance, which constitutes characteristics that could be easily measured. It could also be e.g. complex mathematical formulas, which defines the relationship between different values. However, just like product-by-process claims these parameters risk creating legal uncertainties, especially when one refers to parameters that are previously unheard of or are unconventional.[85]

2.2.3 EU law affecting the patent term in the pharmaceutical industry

In the EU there are, even though the patent system is not an EU system, some important EU regulations affecting the pharmaceutical industry and, thus, pharmaceutical patents as well.[86] They will shortly be described here in order to demonstrate the complexity of the pharmaceutical industry. The Supplementary Protection Certificate ("SPC") is based on Regulation(EC) No 469/2009[87] and provides an extended term of protection for medicinal products after the expiry of a patent. It is used to encourage research in the pharmaceutical industry. The extended protection concerns the active substance, i.e. only the product.[88]

The SPC was created due to the authorisation procedure that those active substances have to undergo before they can be sold within the EU internal

[84] Bengt Domeij (n 39) 67-69.
[85] ibid 69-70.
[86] ibid 268, 271.
[87] Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L 152/1.
[88] Bengt Domeij (n 39) 268, 271.

market, as it can take several years. Without the SPC the incentivising effect would have been limited, as the patent owner would have had less time to exploit the benefits of their patent.[89] The marketing authorisation ("MA") can be provided through a centralised authorisation procedure, based on Regulation(EC) No 726/2004[90]. This means one single MA for the entire EU.[91] A MA can also be provided through national authorisation procedures.[92]

[89] Justine Pila, Paul Torremans (n 41) 213.
[90] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1.
[91] 'Authorisation procedures – the centralised procedure' (*European Commission)* <https://ec.europa.eu/health/authorisation-procedures-centralised_en> accessed 2 April 2021.
[92] 'Authorisation procedures – national authorisation procedures' (*European Commission*) <https://ec.europa.eu/health/authorisation-procedures-national_en> accessed 2 April 2021.

3 Plausibility at the EPO

In the sections below follows a deepened review of predominant case law on the topic of plausibility in relation to inventive step under Article 56 EPC as well as sufficiency of disclosure under Article 83 EPC. This is furthermore followed by an analysis on what have been displayed through the case law combined with opinions from the legal doctrine, in order to answer to if there is an even application of the plausibility threshold at the EPO.

3.1 Plausibility in relation to inventive step

The requirement of an inventive step is found in Article 56 EPC. The first part of the Article reads: 'An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.'[93] As stated in the EPO Guidelines, when assessing an inventive step the problem-solution approach is used. It consists of three steps, namely (1) determine the prior art, (2) establish the objective technical problem that shall be solved and (3) consider if the claimed invention would be obvious for the skilled person, when looking at the prior art and the objective technical problem.[94]

It is in the second step where the plausibility threshold is applied, as will be displayed in the case law below. In the EPO Guidelines it is furthermore stated that only if it is found *credible* that substantially all compounds in a claim exhibits a technical effect, a technical problem can be considered solved.[95] This is clearly taken from T 939/92 *AgrEvo*[96]. There are, however, some conflicting opinions in the legal doctrine regarding if T 939/92

[93] Article 56, European Patent Convention.
[94] *Guidelines for Examination in the European Patent Office* (EPO Guidelines, the European Patent Office March 2021) Part G, Chapter VII 2-3.
[95] ibid 5.
[96] T 939/92 *AgrEvo/Triazole sulphonamides* OJ EPO 1996, 309.

AgrEvo actually concerned plausibility, which will be further explored[97] as well.

3.1.1 Case T 939/92 AgrEvo

The plausibility threshold is generally believed to have been firstly established in case T 939/92 *AgrEvo*.[98] This case concerned an appeal against a decision of the examining division, refusing a patent application claiming a large amount of triazole sulphonamide compounds, via a so called Markush type claim[99]. The main legal issue of the case was a discussion on the concept of technical contribution under Article 56 EPC. The Board expressed in that regard, based on previous case law of the EPO, that it had been established that a patent monopoly is justified by, and should correspond to, the technical contribution to the art. Thus, constituting a generally accepted legal principle.[100]

The Board further stated that an arbitrary choice from different possible solutions to a technical problem could not be regarded as involving an inventive step.[101] According to the Board the choice of compounds must instead, in order to be patentable, 'be justified by a hitherto unknown technical effect which is caused by those structural features which distinguish the claimed compounds from the numerous other compounds'.[102] The Board continued with establishing that the technical effect must be "fairly assumed" to be produced by substantially all the selected compounds in order to justify the selection of those compounds. The Board also found the burden of proof in that regard to lie on the person alleging that, when it is "inherently unlikely" that all, or at least a substantial

[97] See section 3.3.1.
[98] See e.g. Edward Cronan 'Plausibility after Warner-Lambert v Actavis: fantastic legal tests and where to find them' (2019) Vol. 14 No. 7 JIPLP 552, 558.
[99] See section 4.1 for a description of these kind of claims.
[100] See Andrew J K Wells (n 1) 785 and T 939/92 *AgrEvo* (n 96) paras I, 2.4.2.
[101] T 939/92 *AgrEvo* (n 96) para 2.5.3.
[102] ibid.

part of, the claimed compounds would possess the activity that has been promised.[103]

The fact that the appellant only had results proving that *some* of the claimed compounds were herbicidally active was, according to the Board, not sufficient in this case to prove that *substantially all* the claimed compounds had those qualities. This, as it was not considered common general knowledge for the person skilled in the art to, based on the information disclosed in the application, figure out that the claimed compound was herbicidally active. Moreover, it was stated by the Board that it is considered common general knowledge that even the smallest structural modifications may cause very large differences to biological activity.[104] Thus, the Board found that it had not been provided enough data proving herbicidal activity in substantially all of the claimed compounds within the Markush type claim. The claims were therefore considered to have been arbitrarily selected.[105] The appeal was, thus, rejected and the grant of the patent was denied.[106]

3.1.2 Case T 1329/04 John Hopkins

According to some within the legal doctrine, T 1329/04 *John Hopkins*[107] is instead the case where the plausibility threshold was first established.[108] In this case the subject matter of the claims was considered lacking an inventive step under Article 56 EPC, resulting in the appeal being dismissed in its entirety. The application stated that the aim of the invention was to find and isolate a further member of the TGF-β superfamily. The application specifically mentioned GDF-9 as such a new member being found.[109] The TGF-β superfamily was described by the applicant to contain structurally related proteins. These proteins were furthermore described to, in many

[103] T 939/92 *AgrEvo* (n 96) paras 2.5.3, 2.5.4, 2.6.1.
[104] ibid para 2.6.2.
[105] Andrew J K Wells (n 1) 785.
[106] T 939/92 *AgrEvo* (n 96) 1, 23.
[107] T 1329/04 *Factor-9/JOHN HOPKINS* of 28 06 2005.
[108] Andrew J K Wells (n 1) 786.
[109] T 1329/04 *John Hopkins* (n 107) paras 1, 2, 4, 5, 15.

different ways, affect differentiation processes which occur during embryonic development.[110]

However, the GDF-9 sequence was in the application admitted to significantly diverge from the other TGF-β family members' sequences. This finding could according to the Board put GDF-9, at best, in a yet unidentified subgroup to the family. This, was also combined with the fact that the most striking structural feature of the TGF-β family, namely that they have seven cysteine residues present, was not present within GDF-9 which only had six.[111]

As GDF-9 were missing identical significant structural features with the TGF-β superfamily, as displayed in the paragraph above, as well as no functional characterisation of it was presented within the application, it according to the Board had not been sufficiently identified that GDF-9 was a part of the family.[112] The Board further stated that, 'there is not enough evidence in the application to make at least *plausible* that a solution was found to the problem which was purportedly solved'.[113] Thus, the requirement of inventive step was not fulfilled as the plausibility threshold was not reached.

3.1.3 Case T 488/16 Dasatinib/BRISTOL-MYERS SQUIBB

The EPO case T 488/16 *Dasatinib*[114] is more recent, dating from 2017, and concerned inventive step and plausibility of a patent defined by a Markush type claim. In this case the patent had been revoked by the opposition division as it was considered novel, but lacking an inventive step. Post-published data had been submitted as evidence, but was not taken into

[110] Andrew J K Wells (n 1) 786.
[111] T 1329/04 *John Hopkins* (n 107) paras 7, 8, 10.
[112] ibid para 11.
[113] ibid (emphasis added).
[114] T 488/16 *Dasatinib/BRISTOL-MYERS SQUIB* of 01 02 2017.

consideration by the opposition division as the technical effect of the invention had not been *plausibly* demonstrated at the filing date. The patent concerned the compound dasatinib which, according to the appellant claims has protein tyrosine kinases ("PTKs") inhibitory activities. These PTKs inhibitory activities could particularly be used for treating cancer. The patent owner appealed the decision of the opposition division to the BoA.[115]

The documents that the applicant had submitted as evidence of the technical problem being solved were also, according to the Board, not to be taken into consideration in the assessment of inventive step. This, as they were post-published; filed more than three years after the filing of the patent, but still *the first evidence* of the solution to the claimed technical problem. The appellant had on the other hand argued that there is no requirement of experimental proof in order to meet the plausibility threshold under Article 56 EPC. They furthermore argued in that regard that the summary statement they had provided was enough in order to meet the (according to them) low plausibility threshold that should be met.[116]

However, the Board clarified that even though it is not always required to have experimental data in the application, the technical problem must at least have been shown to be *plausibly* solved at the filing date. It was not considered acceptable, by the Board, to draw up a generic formula, covering millions of compounds, which left it to the person skilled in the art to on their own figure out which compound inhibits which kinase and can be used for treating respective diseases associated with it. The Board moreover emphasised that the problem in this case was that there was an absence of verifiable data regarding the claimed technical effect, not that there was no experimental data provided as proof.[117]

[115] T 488/16 *Dasatinib* (n 114) paras I, IV, 5.1.
[116] ibid paras 4.1, 4.8, 4.19.
[117] ibid para 4.9.

According to the board there were, thus, no evidence within the patent stating that dasatinib successfully could be used for treating cancer. The post-published documents submitted by the appellant could not be taken into consideration for the reasons stated above. The board therefore came to the conclusion that the problem to be solved only concerned the finding of a new chemical compound and that, based on previous EPO case law, chemical compounds are not patentable merely because of their originality. Thus, the inventive step requirement in Article 56 EPC was not fulfilled.[118]

3.2 Plausibility in relation to sufficiency of disclosure

The requirement of sufficiency of disclosure is found in Article 83 EPC, which reads as follows: 'The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.'[119]

Currently, in the EPO Guidelines it is stated that there should be a detailed description of at least one way of carrying out the invention for it to be sufficiently disclosed under Article 83 EPC. It is the person skilled in the art that shall be able to carry out the invention. How much information that has to be displayed varies from case to case, depending on the different facts and evidence. Sometimes very broad fields are described by few or only one example, and those applications are still found to be sufficiently disclosed. In those cases, there is, in addition to the example, a need for sufficient information that makes it possible for the skilled person to, based on their common general knowledge, perform the whole invention without undue burden and inventive skills.[120]

[118] T 488/16 *Dasatinib* (n 114) paras 5.5, 5.6, 5.7.
[119] Article 83, European Patent Convention.
[120] EPO Guidelines (n 94) Part F, Chapter III 1.

The plausibility threshold is mentioned within the EPO Guidelines under Article 83 EPC in relation to burden of proof. With a reference to T 1329/04 *John Hopkins* the Guidelines describes that if it is not, at least, made *plausible* that the claimed invention can be carried out, the general rule of burden of proof on the objecting party does not apply. In that case the applicant must be able to prove that the invention can be carried out instead.[121]

3.2.1 Case T 609/02 Salk

In contrast to the cases above, case T 609/02 *Salk*[122] concerns Article 83 EPC and, thus, the plausibility threshold in relation to sufficiency of disclosure. The patent in this case claimed the use of a steroid hormone by a specific method for the treatment of diseases such as asthma, rashes and arthritis, which were stimulated by a substance called AP-1. Thus, the claim concerned a substance for a medicament to be used in a specific therapeutic application, constituting a so called "medical use claim". However, the Board did not find any evidence at all within the patent specification that the steroid hormone could have any impact whatsoever over the diseases mentioned. There were thus no technical basis found by the BoA for the claims made.[123]

The Board also stated that the requirement of sufficiency of disclosure had to be fulfilled at the effective date of the patent – in difference to what the appellant had claimed. Thus, this would be based on the information provided within the patent application as well as the common general knowledge of the skilled person at that date. Anything else would, according to the Board, be the granting of a patent for an invention that had actually been made after the effective date of the patent. The Board found that this would, furthermore, go beyond the general principle which states that the monopoly a patent provides, should correspond to and be justified by the

[121] EPO Guidelines (n 94) Part F, Chapter III 3.
[122] T 609/02 *AP-1 complex/SALK INSTITUTE* of 27 10 2004.
[123] ibid paras 3, 5, 9.

technical contribution to the art[124], which was also mentioned by the board in T 939/92 *AgrEvo* as displayed above.

Moreover, the Board stated that, under Article 83 EPC, the application must display the suitability of the product to be manufactured for the therapeutic application claimed, unless the suitability is already known by the person skilled in the art at the priority date. However, it is not always necessary to be able to prove results based on clinical trials. But to simply state that a compound could be used for a specific treatment, like in the present case, without any evidence for it, was not considered sufficient by the BoA in order to fulfil the requirement of disclosure.[125] The Board found the patent specification simply to be, 'a vague indication of a possible medical use for a chemical compound yet to be identified, (…)'.[126] The Board stated in that regard that for example information in the form of experimental tests could be provided as a basis for technical effect. Thus, there is the requirement to make the existence of a cause/effect relationship *plausible*.[127]

3.2.2 Case T 950/13 Dasatinib in the treatment of chronic myelogenous leukaemia/BRISTOL

In this second case concerning dasatinib – T 950/13 *Dasatinib in the treatment of CML*[128]*,* also from 2017, the question concerned plausibility in relation to sufficiency of disclosure under Article 83 EPC instead of inventive step which the first case did. This case concerned a second medical use claim, where it was stated in its Claim 1 that dasatinib would be used for producing a medicament for treating chronic myelogenous

[124] T 609/02 *Salk* (n 122) para 8.
[125] ibid para 9.
[126] ibid para 13.
[127] ibid paras 9, 10.
[128] T 950/13 *Dasatinib in the treatment of chronic myelogenous leukaemia/BRISTOL* of 03 02 2017.

leukaemia ("CML"). The patent owner had appealed the decision of the opposition division, which was a revocation of that patent.[129]

However, the Board came to a different conclusion than the opposition division, finding the claim of dasatinib being suitable in treating CML as clearly disclosed in the patent application. The patent application concerned the use of compounds, that had been defined generically, for the treatment of certain types of cancer. The compounds were used for this as they were said to inhibit PTKs' such as SRC, BRC-ABL and c-KIT. Dasatinib was the only compound that was identified within the application for being suitable for the said treatment and methods for the administration of it were displayed.[130]

According to the Board, even if claim 4 did not explicitly refer to CML, it was, based on what was commonly known at the filing date of the patent application, clear for the person skilled in the art that CML was included within the cancers that was referred to in this claim.[131] The Board furthermore accepted the argument by the applicant that it would have been within the common general knowledge of a person skilled in the art that they could have tested dasatinib for inhibiting BRC-ABL PTKs, even though there was no experimental evidence for it within the application. In addition, there could not be any *a priori* serious doubts of the skilled person for dasatinib to be able to inhibit BRC-ABL PTKs, as evidence had been disclosed within the application that it inhibited activities of other PTKs.[132]

Finally, dasatinib had functional equivalence to imatinib, which had been established to be an effective inhibitor of BRC-ABL PTKs and, furthermore, to treat CML. Based on all of this, the Board found the application to at least display a *plausible* technical concept. Therefore, they

[129] T 950/13 *Dasatinib in the treatment of CML* (n 128) paras I, 3.2.
[130] ibid paras 3.3, 3.4.
[131] ibid para 3.4.
[132] Matthew Royle, Paul England 'Plausibility after pregabalin – how much information must a patent disclose?' (2019) issue 96 July/August IAM 76, 79-80.

also did not found any reasons for why a skilled person would find this concept implausible in advance, in relation to Article 83 EPC. In such a situation post-filed data could furthermore be taken into consideration as it would only strengthen what had already been established within the application.[133]

3.3 An even application of the plausibility threshold at the EPO?

My position is that there is an uneven application of the plausibility threshold at the EPO. This, as the EPO case law have created uncertainties regarding, for example, what really falls under the concept of plausibility[134], how much data that has to be displayed in the patent application and, thus, when the applicant should file for a patent[135]. These uncertainties also result in questions as to how this newly developed plausibility threshold will affect earlier granted patents[136]. In the following sections these, and some other problems, are further displayed. Within the application procedure it is foremost uncertainties for the applicants, but potential competitors might be affected as well as any unclear case law of the EPO also have an impact on national case law[137].

3.3.1 The origin of plausibility?

There are different opinions in the legal doctrine as to when the plausibility threshold was first applied; either T 939/92 *AgrEvo* or T 1329/04 *John Hopkins*. This is interesting and intriguing and in my opinion, reveals the level of uncertainties regarding what is really falling within the concept of plausibility. How broad is it really, and how and when is it applied? It is furthermore noteworthy that the threshold completely developed through the

[133] T 950/13 *Dasatinib in the treatment of CML* (n 128) paras 3.5, 3.6.
[134] See section 3.3.1.
[135] See section 3.3.3.
[136] See section 3.3.5.
[137] See chapter 5 in this regard.

case law of the EPO. As the plausibility threshold is not to be found within the EPC, my position is that this contributes to even more uncertainties[138].

It appears to be a dominating view within the legal doctrine that the plausibility threshold was first established in T 939/92 *AgrEvo*[139]. This view comprises that this case established that for an invention to be patentable its technical contribution must be found plausible, despite the fact that the TBA did not use the term "plausible" specifically. Instead the TBA stated that the claimed technical effect must be found to be "credible", "fairly assumed" or "reasonably predictable". As they did not find the patent to be so, it was held to be invalid based on Article 56 EPC.[140] England is of the opinion that the plausibility threshold was first established in T 939/92 *AgrEvo* through the Board's usage of those expressions. England further argues that the concept continued developing through T 1329/04 *John Hopkins*, when the term "plausibility" was first mentioned.[141] Cronan is also stating that plausibility under inventive step has been examined, in the UK case law, on the basis of T 939/92 *AgrEvo*.[142]

However, there are others in the legal doctrine who, on the other hand, believe the plausibility threshold to have been established much later than in T 939/92 *AgrEvo*. Wells argues that the statement of the Board in T 939/92 *AgrEvo*, that the technical effect should be found "credible", was simply a way to describe the "standard of proof" the TBA followed in relation to the assessment of evidence presented, when deciding if a technical problem in fact had been solved. Wells instead believe the plausibility threshold to have been established in T 1329/04 *John Hopkins*.[143] These divided opinions regarding if T 939/92 *AgrEvo* really concerned plausibility, must in my opinion be sorted out, as the concept of plausibility cannot be applied in a

[138] Something that will be discussed further in chapter 6.
[139] This is my position due to the prevailing number of articles found displaying this view.
[140] See e.g. Paul England, 'Patents and plausibility' (2014) Vol. 9 No. 1 JIPLP 22, 22-23 and Miquel Montañá (n 11).
[141] Paul England (n 140) 23.
[142] Edward Cronan (n 98) 558.
[143] Andrew J K Wells (n 1) 786.

legally certain way unless it is really clear what falls under it. This is my position as an unclear application of the plausibility threshold by the BoA does not only create uncertainties for the applicants or third parties in the pre-grant procedure, but also that it clearly creates uncertainties regarding the application of the threshold on a national level[144], for patent owners and third parties, in the post-grant procedure.

3.3.2 Different threshold under Article 56 and Article 83 EPC?

As interestingly argued by England and Royle, one can make a comparison between the two (pretty similar in facts) *dasatinib* cases, case T 488/16 *Dasatinib*[145] and T 950/13 *Dasatinib in the treatment of CML*[146]. Specifically make a comparison of how the plausibility threshold was applied, and considered, in them by the Boards. In the first one, regarding plausibility in relation to inventive step, the Board came to the conclusion that the technical effect had not been made plausible. In the second one, regarding plausibility in relation to sufficiency of disclosure, the Board on the other hand came to the conclusion that the application displayed a plausible technical concept.[147] They thus, intriguingly landed on different sides of the plausibility threshold despite the facts of the cases being quite similar.

Could the comparison in the paragraph above be proof of the plausibility threshold being in need of further clarification in order to create legal certainty? England and Royle is at least not of such an opinion. They make a division between *per se* claims and second medical use claims when examining plausibility. In the first kind of pharmaceutical patent cases one examine if the plausibility threshold is reached in relation to inventive step

[144] See more about the post-grant procedure and the application of the plausibility threshold in chapter 5.
[145] See section 3.1.3.
[146] See section 3.2.2.
[147] Matthew Royle, Paul England (n 132) 79.

and in the other kind of cases one examine it in relation to sufficiency. Even though this difference exist the authors believe that there is the same need under both provisions to demonstrate plausibility. England and Royle also find the plausibility test to be the same, despite the different outcomes in the two dasatinib cases.[148]

However, in my opinion, the application of the plausibility threshold is not as clear cut as England and Royle claim. The fact that T 488/16 *Dasatinib* and T 950/13 *Dasatinib in the treatment of CML* were similar in fact but still landed on different sides of the plausibility threshold, is in my opinion rather creating uncertainties as to if the threshold was (and is) applied similarly under Article 83 EPC and Article 56 EPC by the Boards. My position, that there are overall uncertainties surrounding the plausibility threshold, is further substantiated by the several other problems connected to it, like the uncertainties regarding the amount of data needed to be provided in the application to fulfil the threshold or the burden of proof in regards to a reformulated technical problem, as is displayed below.

3.3.3 How much data must be displayed in the patent application?

Whiting, a legal practitioner also expressed a different position to the one of England and Royle, when being a panellist at the Fordham IP Conference in 2019. According to Whiting the problem lies in the fact that there are uncertainties, when looking at the EPO case law, regarding how much data that must be displayed in the patent application for reaching the plausibility threshold; sometimes experimental data is required and sometimes not, which creates uncertainties for the applicants.[149]

[148] Matthew Royle, Paul England (n 132) 80.
[149] Annsley Merelle Ward, 'Fordham 27 (Report 8): Second Medical Use/Plausibility' (*The IPKat*, 28 April 2019) <https://ipkitten.blogspot.com/2019/04/fordham-27-report-8-second-medical.html> accessed 14 March 2021.

Similar uncertainties as those displayed by Whiting, have also been pointed out by Burrichter, Kirchhofer and Müller. The authors express that after T 488/16 *Dasatinib* the question as to when the applicant should file for a patent has become even more complex. Based on the first-to-file principle it is important to file quickly, in order to ensure that no one does it before you; making your invention non-patentable. However, Burrichter, Kirchhofer and Müller argue that, after T 488/16 *Dasatinib,* the applicant has to be careful not to apply for a patent too early. This, as the authors argue that the applicant, in the application, must include a large amount of experimental data. If not, the applicant should at the minimum include descriptions in detail of the experimental methods used to establish the claimed technical effect, in order to ensure that the effect has been made plausible.[150]

Thus, if these requirements of providing experimental or verifiable data will be applied generally in the following case law of the EPO, it will in my opinion indicate that there is a newer, higher, plausibility threshold that has to be complied with. This as, in line with what was expressed by Whiting above, it has previously not been clear what amount of data (and the quality of it) that is required in the patent application in order for it to reach the plausibility threshold. If a large amount of data is now always required, that indicates the application of a higher plausibility threshold.

It is, however, in this regard important to keep in mind that the same year as T 488/16 *Dasatinib* came, the decision in T 950/13 *Dasatinib in the treatment of CML* came as well, based on similar facts. In this second case[151] there was no need to provide experimental data in order to prove that the application had made the claimed technical effect plausible, as any questions that arose was considered falling within the common general knowledge of the person skilled in the art. Thus, it is in my opinion still unclear if the threshold has been generally heightened or not. Moreover,

[150] Arwed Burrichter, Natalie Kirchhofer, Simon Müller 'Clinical trial disclosures – an obstacle to patentability in Europe' (*IAM*, 14 May 2019) <www.iam-media.com/clinical-trial-disclosures-obstacle-patentability-in-europe> accessed 23 April 2021.
[151] See section 3.2.2.

another aspect to consider is that any unclarities regarding what should be considered falling within the common general knowledge of the person skilled in the art will also create uncertainties regarding the amount of data needed for reaching the plausibility threshold. This, as the more that is considered falling within the common general knowledge, the less information has to be provided within the patent application for it to reach the plausibility threshold (and the other way around).

England and Royle also mention this tension between the commercial interest to file as fast as possible (because of the first-to-file principle) and the need for providing enough information/data within the patent application in order to justify the monopoly a patent provides. This is generally called the "applicants dilemma".[152] Any potential uncertainties regarding if the plausibility threshold have been heightened or not, will according to me, make this dilemma even harder for the applicants. This will be extra clear in relation to Markush type claims[153], as their technical effect is already generally burdensome to prove due to the complexity of this type of claims. Thus, my position is that if applicants with inventions based on Markush type claims are unsure if the threshold has been heightened or not, they might hesitate in applying for patents, which risk hinder innovation.

3.3.4 The burden of proof

Another aspect that has to be taken into consideration are the possible uncertainties as to who has the burden of proof regarding if a technical effect has been made plausible or not, and the scope and standard of evidence required. As Kutik and Renken mentions, both the assessment under Article 56 and 83 EPC are made to ensure that speculative patents are not being granted. The authors moreover state, that the choice of making an assessment of the presence of a technical effect either under inventive step

[152] Matthew Royle, Paul England (n 132) 76.
[153] See section 4.2.3.

or sufficiency depends on the drafting of the claims.[154] This interestingly differ to how England and Royle make the division[155].

Kutik and Renken further argue that, in line with what Whiting expressed[156], there are uncertainties regarding if the solution to a reformulated problem must have been displayed (made plausible) by the applicant already within the application as filed. The authors point out that this can put the applicant in an extremely difficult situation as they might not have been aware of any newly cited prior art at the filing date, making it even more difficult to prove an inventive step over it. The BoA have based these kind of demands on T 1329/04 *John Hopkins*, but Kutik and Renken find it to have been done incorrectly as T 1329/04 *John Hopkins* refers to plausibility in relation to the problem that the application sets out to solve – not the objective technical problem.[157] In my opinion, the different interpretations of for example T 1329/04 *John Hopkins* is yet another proof of the uncertainties as to how the plausibility threshold should be applied, specifically affecting the applicants but also any competitors operating within the pharmaceutical sector and using patents as a part of their overall business strategy.

3.3.5 Retroactive application of plausibility

As argued by Montañá, another aspect concerning legal certainty for the patent owners is the retroactive application of plausibility to patents that were granted long before the plausibility threshold was developed through the case law of the court.[158] This recently developed threshold was of course nothing those patent owners could foresee and, thus, prepare for. What is then, in my opinion, making everything even more uncertain for the patent owner is the uneven application of the plausibility threshold in the current

[154] S. Kutik, J. Renken 'Who bears the burden to show that an objective technical problem has been credibly solved?' (2019) no. 3/19 EPI Information September 17, 17.
[155] See section 3.3.2. They made a clear division between per se claims and second medical use claims.
[156] See section 3.3.3. Whiting expressed that the problem lies in the uncertainties for the applicants regarding how much data that must be displayed in the patent application.
[157] S. Kutik, J. Renken (n 154) 20.
[158] Miquel Montañá (n 11).

case law of the EPO, as displayed in the previous sections. This affect the application of the plausibility threshold in national jurisdictions as well, for example in invalidation procedures, as the national courts to a large extent follow the case law of the EPO[159]. Thus, both for the pre-grant and post-grant procedure it is crucial with an even application of the plausibility threshold at the EPO, which we do not have at the moment.

[159] See chapter 5.

4 The Markush type claims

In the sections below follows a deepened review of the Markush type claims, specifically examining the burden of proof and non-working embodiments. This is furthermore followed by an analysis on what have been displayed throughout the chapter combined with opinions from the legal doctrine and some of the case law from chapter 3, in order to answer to if the Markush type claims originate any specific issues regarding the plausibility threshold. This as there is a risk for legal certainty issues arising in relation to patents and patent applications which by their very nature have a wide scope. However, on the other hand, structural formulas like the Markush type claims have been considered as the most precise and appropriate way of defining chemical compounds[160] and are thus important for the pharmaceutical sector.

4.1 Background to Markush type claims

The Markush type claims are named after Dr. Eugene Markush, who in 1924 was the first to successfully use this type of claims in a patent application before the United States Patent and Trademark Office ("USPTO").[161] As mentioned above[162] the Markush type claims are structural formulas, and more precisely "generalised structural formulas". They are, according to Domeij, the most precise way to define chemical compounds, when compared to the other alternatives existing. The Markush type claims are furthermore specifically considered to enable a concise way of defining a very large number of compounds.[163]

[160] See section 4.1.
[161] Peter Geyer 'Markush structure searching by information professionals in the chemical industry – Our views and expectations' (2013) 35 World Patent Information 178, 178.
[162] See section 2.2.2.
[163] Bengt Domeij (n 39) 68.

But what does these Markush type claims really compose of? The EPO Guidelines states that so called "Markush groupings" are claims that within one single claim define several different alternatives. These can either be chemical or non-chemical.[164] As expressed by Geyer, "Markush structures" comprises one core chemical structure together with a list attached of its possible substitutes. These are normally called R-groups.[165] In T 1020/98[166] it was clarified by the BoA that the fact that Markush type claims are usually complex because of their size, does not mean that the patent claim should be regarded by the examiner as unclear under article 84 EPC.[167] The complexity of Markush type claims have, according to Geyer, only continued to increase, resulting in longer and more complex descriptions of them.[168]

In relation to this type of claims Article 82 EPC as well as Rule 44 of the Implementing Regulations[169] should be mentioned. There is, in Article 82 EPC, a requirement regarding the unity of the invention. This requirement concerns all inventions, stating that a patent application shall either refer to one invention or a group of inventions that are linked in a way which makes them form a "single general inventive concept".[170] Thus, this article ensures that there is only one claimed invention within a patent application.[171]

Rule 44 of the Implementing Regulations is more specifically explaining the requirement of unity of the invention under Article 82 EPC when it comes to grouping of inventions. In the first paragraph it is established that, for a finding of unity, there has to be same or corresponding special technical

[164] EPO Guidelines (n 94) Part F, Chapter V 9.
[165] Peter Geyer (n 161) 178.
[166] T 1020/98 *Safeners/BAYER* of 27 6 2003.
[167] Åsa Andersson, Katarina Söderberg (n 76) 24.
[168] Peter Geyer (n 161) 178.
[169] Implementing Regulations to the Convention on the Grant of European Patents of 5 October 1973 as adopted by decision of the Administrative Council of the European Patent Organisation of 7 December 2006 and as last amended by decision of the Administrative Council of the European Patent Organisation of 27 March 2020 (Implementing Regulations).
[170] Article 82, European Patent Convention.
[171] Bengt Domeij (n 39) 78.

features existing; defining a technical relationship between the alternatives within the claim. In the second paragraph it is furthermore stated that for the finding of a "single general inventive concept" in Article 82 EPC it is not relevant if the inventions are claimed in separate claims or alternatives within one single claim.[172] The second alternative being applicable to the Markush type claims.

It is stated within the EPO Guidelines that these same or corresponding special technical features in Rule 44(1) of the Implementing Regulations, when it comes to Markush type claims, are considered met when the alternatives are of a "similar nature". This somewhat vague notion is furthermore explained to be met when (1) there is a common activity or property to all the alternatives and (2) there is a common structure present. What is meant with the second condition is that they either share a significant structural element or that all the alternatives belong to a recognised class of chemical compounds.[173]

The above mentioned "significant structural element" under the second condition is explained within the EPO Guidelines to concern the technical contribution which the claimed invention, as a whole, makes over prior art. It furthermore means either that the alternatives share a common chemical structure occupying a large portion of their structures, or that they share a small portion of their structures but that one is structurally distinctive and, thus, leading to a technical contribution over prior art. The "recognised class of chemical compounds" under the second condition means that members of the class could be substituted with each other, with the expectation of the achievement of the same intended result. Moreover, what is important to bear in mind is that if one of the alternatives within the Markush type claim is not considered to be novel, the unity of the invention (as a whole) should be questioned.[174]

[172] Rule 44, Implementing Regulations.
[173] EPO Guidelines (n 94) Part F, Chapter V 9.
[174] ibid 9-10.

4.1.1 Burden of proof

The procedural rules have an increased importance in cases concerning Markush type claims. This, as there are difficulties in defining a firm legal basis for the assessment of the breadth of the claims, and therefore, since neither the applicant nor the examiner has the practical opportunity to examine if there is any technical effect, the burden of proof is crucial.[175] The general rule, as stated in the EPO Guidelines, is that a claim should be regarded by the examiner as being supported by the presented description. This will however not be the case when there are well-founded reasons to believe that the person skilled in the art would not be able to, by experimenting or using routine methods, extend the teaching of the description to its whole claimed field on the basis of the information provided within the application. If the examiner have concluded that there is such a lack of support, it is instead the applicant that has to prove that the claim is fully supported.[176]

Thus, it is primarily the examiner that has to prove that the claim is too broad. But, as stated by Domeij, T 939/92 *AgrEvo* is interesting in this regard as the burden of proof in that case shifted to the applicant. The BoA stated in that regard that the one supporting their application on a certain fact, also have to be able to prove that fact. Domeij, however, points out that it is only in rare cases that the applicant has had to prove why their generalisation is reasonable. It is moreover only in extreme cases that the application has been rejected due to "unreasonable generalisations".[177]

4.1.2 Non-working embodiments

As of the low predictability within the biological field, there are difficulties in assessing if the technical effect is present throughout the whole scope of

[175] Bengt Domeij (n 39) 80.
[176] EPO Guidelines (n 94) Part F, Chapter IV 37-38.
[177] Bengt Domeij (n 39) 80-81.

protection of the invention[178]. This low predictability, moreover, results in the fact that claims comprising of thousands of compounds (or more) must be expected to also include so called non-working embodiments. However, the BoA has sometimes required that all parts of the patent claims must be functional. Domeij, points out that the legal situation might seem clear, but that it is actually far from that. In other EPO cases it has been, at least, indicated that an absolute requirement of functionality cannot be upheld. This was for example the situation in T 939/92 *AgrEvo*, where it was stated that only "substantially" all parts which is found within the claim must be able to work.[179]

How come the Board sometimes use this more flexible approach, where not all parts of a patent claim must be functional? Domeij describes the necessity to attain such an approach in the pharmaceutical field due to practical problems existing, as it is an unpredictable technical area. The skilled person must in such a technical area be able to make some adjustment for fulfilling the features within the patent claims. What is crucial in such a situation is, however, that it is clear for the skilled person what results they are expected to achieve.[180]

Within the EPO Guidelines the relationship between the Markush type claims and the non-working embodiments is explained. There it is stated that there is no harm in having non-working embodiments in the claims, as long as it is also clearly presented with sufficient information how one should identify the working embodiments within the claims.[181]

[178] See section 4.1.1.
[179] Bengt Domeij (n 39) 82-83. See section 3.1.1 above for a description of the case.
[180] ibid 84-85.
[181] EPO Guidelines (n 94) Part F, Chapter III 3.

4.2 Is there a specific issue with Markush type claims and plausibility?

My position is that in relation to this type of claims, the principle of legal certainty apply to even more aspects, which has to be taken into consideration and, thus, makes the application of the plausibility threshold even more complex. These aspects are for example that the Markush type claims are broad and thus risk creating legal uncertainties regarding what they really comprises (uncertainties for third parties), but also uncertainties as to the level of functionality that has to be proven in the patent application (uncertainties for the applicants). These specific issues, with Markush type claims, have also already been displayed to some extent in the previous chapter, as some of the cases[182] therein concerned this type of claims.

4.2.1 Specific issue related to the burden of proof?

As described above[183], neither the applicant nor the examiner at the granting institution have the practical opportunity of proving technical contribution of an invention based on this type of broad claims. Therefore, it is important to be aware of, at least, who has the burden of proof in this regard. Normally, as also displayed above, the burden only falls on the applicant if the examiner have well-founded reasons to believe that the claimed scope is too broad (in relation to the technical teaching within the application). This, in my opinion seems fair, as one should keep in mind that patents are used as incentives for innovation[184], and that there would be less incentives to go through the entire patent application process if the burden of proof would be too hard on the applicants. On the other hand, a too low bar would also harm innovation since competitors would be deterred from investing in research

[182] See e.g. section 3.1.1 and 3.1.3.
[183] See section 4.1.1.
[184] See section 2.1.4.

and development that risk falling within the scope of a theoretically very broad Markush type claim.

However, what complicate the situation, as argued by Domeij[185] is that this distribution of the burden of proof is sometimes shifting, which it was for example in T 939/92 *AgrEvo*. Even though Domeji points out that it is only in rare cases that the applicants have to prove why it is reasonable to make their generalisation, the fact that it might happen is still, according to my opinion, connected to legal uncertainties for the applicant. When and why should thus be clarified, in order to ensure continued incentives for investing in the development of pharmaceutical patents.

4.2.2 Specific issue related to non-working embodiments?

Non-working embodiments are, as described above[186], generally accepted within Markush type claims. In T 939/92 *AgrEvo* the applicant only had to prove (make plausible) that "substantially all" compounds found within the claim are able to work. This should be compared to the EPO Guidelines where it is stated that there is "no harm" in having non-working embodiments within a claim, as long as it is clear how to find the working embodiments. Thus, in my opinion T 939/92 *AgrEvo* and the Guidelines can either be argued to be in line with one another, as they both accept (to some extent) non-working embodiments. However, on the other hand the Guidelines also express a more general acceptance to non-working embodiments while T 939/92 *AgrEvo* seems to be a bit more restrictive.

My position is that a more restrictive T 939/92 *AgrEvo* approach could possibly be necessary as allowing for too many non-working embodiments within a claim could result in the granting of speculative extensive patent claims, which is also creating uncertainties and an obstacle for further

[185] See section 4.1.1.
[186] See section 4.1.2.

research and development within the technical field theoretically covered by a Markush type claim. These legal uncertainties concern third parties, perhaps competitors on the pharmaceutical market who get trouble knowing if their medicaments infringe patents which are very broad and speculative. That would also risk going against the general principle, mentioned by the board in T 939/92 *AgrEvo*[187] as well as T 609/02 *Salk*[188], that a patent monopoly is justified by its technical contribution to the art and it should, therefore, correspond to it.

4.2.3 Specific issue related to a potentially hightened threshold?

In T 488/16 *Dasatinib*[189] the Board did not find the plausibility threshold to have been reached, as there was no verifiable data of the claimed technical effect presented at the filing date. Could this potentially be regarded as a heightened plausibility threshold and would that be specifically hard on Markush type claims? This question is closely connected to the previously analysed question of burden of proof[190]. Moreover, as stated above[191], neither the applicant nor the examiner have the practical opportunity to examine the technical effect of such broad claims. It is thus difficult as it is to make Markush type claims plausible. However, my opinion is (in line with my expressed position in the section above) that it is necessary, in order to create as much legal certainty for third parties as possible, to have some kind of requirements on the applicants to prove the technical contribution of their inventions. Even though it might create some difficulties for the applicants.

It is clear that the more data required in the application, the more burdensome it will be on the applicant. As stated by Geyer[192] it is in relation

[187] See section 3.1.1.
[188] See section 3.2.1.
[189] See section 3.1.3.
[190] See section 4.2.1.
[191] See section 4.1.1.
[192] See section 4.1.

to this also important to keep in mind that the complexity of Markush type claims has only continued increasing throughout the years. In that regard, it might be important for the Board to continue having a flexible approach, as described above[193], where full functionality of Markush type claims is not required. Thus, allowing for some legal uncertainties for e.g. third parties. However, my position is that T 488/16 *Dasatinib* is at least not posing requirements of full functionality on the applicants, which is important for the continued use of this type of claims for pharmaceutical patents. But, in my opinion it is still clear that the approach of the BoA in T 488/16 *Dasatinib*, is extra hard on applicants relying on Markush type claims since they are, in general, burdensome to prove due to their complexity. Unclarities regarding if the threshold has been heightened or not are also problematic.

The tension between allowing for Markush type claims and providing legal certainty for third parties (like competitors) is in my opinion clear. But, it is in this regard also important to consider the decision of the Board in T 238/88[194], where it was stated that broad claims does not necessarily mean that they lack of clarity. Moreover, one should also consider, as stated by Domeij[195], that structural claims like Markush type claims are the most precise way to define chemical compounds. This compared to the other two alternatives, described above[196], which are product-by-process claims and parameters relating to compounds.

Therefore, even though there are legal uncertainties connected to the Markush type claims, they are still providing more legal certainties than the other options existing. My position is, thus, that in order to ensure the fundamental purpose behind the patent system, namely to provide incentives for innovation, it is crucial not to make the plausibility threshold too high in relation to pharmaceutical patents. A balance between different interests and

[193] See section 4.1.2.
[194] See section 2.2.
[195] See section 4.1.
[196] See section 2.2.2.

aspects must be struck in order to tackle the specific issues that arise in relation to the application of the plausibility threshold.

5 National jurisdictions and plausibility

In the sections below follows a deepened review of plausibility in relation to inventive step as well as sufficiency of disclosure in UK and Swedish case law. This is furthermore followed by a short review of stakeholders view of plausibility, through the 2019 International Association for the Protection of Intellectual Property ("AIPPI")[197] World Congress where plausibility was one of the main topics discussed. Lastly follows an analysis on what have been displayed through the case law combined with opinions from the legal doctrine, in order to answer to if the plausibility threshold has been applied evenly within and between different national jurisdictions.

5.1 UK approach

As previously displayed[198], the UK changed their patent law in order to give effect to the EPC. As will also be displayed through the case law below, the UK courts highly rely on EPO case law when deciding in cases concerning patent law and, specifically, the application of the plausibility threshold.

UK patent law is regulated through the Patents Act 1977. The general patentability requirements are stated in its section 1(1), where inventive step is included. In section 3 of the Patents Act 1977 it is further stated what constitutes an inventive step in relation to obviousness. The requirement of sufficiency of disclosure is stated within section 14(3) of the Patents Act 1977. If the requirement of inventive step is not being fulfilled the granted patent may be subject to revocation under its section 72(1)(a). Furthermore,

[197] AIPPI is the leading politically neutral, non-profit organisation working with the protection of intellectual property rights with the aim to develop and improve the laws, treaties and agreements within that legal area, see 'About AIPPI' (*AIPPI*) <https://aippi.org/about-aippi/> accessed 3 March 2021.
[198] See section 2.1.2.

if the requirement of sufficiency of disclosure is not being fulfilled, the granted patent might be revoked under section 72(1)(c).

5.1.1 Generics v Yeda

The case Generics (UK) Limited t/a Mylan v Yeda Research and Development Co. Limited[199] concerned an appeal of a decision, authored by Justice Arnold ("Arnold J") where Mylan was seeking a revocation of the UK part of an European Patent belonging to Yeda (and licensed by Teva) as well as a declaration of non-infringement, as they wanted to launch their own product within the UK. The patent concerned an improved composition of copolymer-1, which is a synthetic mixture of polypeptides, used in the treatment of multiple sclerosis ("MS"). Mylan questioned the validity of the patent based on grounds such as obviousness (i.e. inventive step) and insufficiency.[200] For the relevance of this essay, the claims concerning obviousness will be examined further as it was in relation to those that plausibility was actualised.

Arnold J classified, in the appealed judgment, the technical effect as less irritation at the injection site caused by copolymer-1 as claimed, and/or reduced cases of systematic side effects caused by it. The judge found that the patent specification had made this technical contribution plausible. Arnold J further stated that a technical effect made plausible by the patent specification, could not be challenged by the use of post-dated evidence.[201]

Lord Justice Floyd ("Floyd LJ"), in the judgment of the Court of Appeal, stated that technical effect was a concept that had been developed by the EPO in relation to the "problem and solution approach" when examining inventive step under Article 56 EPC. Floyd LJ then went on and thoroughly examined both T 939/92 *AgrEvo* and T 1329/09 *John Hopkins*, and

[199] *Generics (UK) Limited t/a Mylan v Yeda Research and Development Co. Limited (Generics v Yeda)* [2013] EWCA Civ 925, [2014] R.P.C. 4.
[200] ibid [H2] - [H3].
[201] ibid [H7].

subsequently, summarised the information that could be taken from them into seven points. He, however, argued that none of those preceding authorities regulates what happens when a technical effect, that had been made plausible in the patent specification, turns out not to exist in fact.[202] Something that, in my opinion, is an interesting observation, adding another layer to the concept of plausibility and the questions surrounding it.

Floyd LJ furthermore disagreed with the finding of Arnold J that Mylan could not challenge a technical effect that had been made plausible in the patent specification with subsequent evidence relating to the true nature of the advance made by the invention. Floyd LJ however stated that it is still the party attacking the patent (Mylan) that has to prove it to be obvious in the light of what was commonly known by the skilled person at the priority date. Mylan was not able to convince Floyd LJ in this regard.[203] As argued by Wells, there is thus presented a two folded test by the judge in relation to inventive step, namely (1) if the technical effect is made plausible by the specification (T 1329/04 *John Hopkins*) and (2) if there is actually a technical contribution in fact (T 939/92 *AgrEvo*).[204]

5.1.2 Generics v Warner-Lambert

The case Generics (UK) LTD (T/A Mylan) v Warner-Lambert Company LLC[205] concerned several cases that had been appealed (and cross-appealed) to the UK Supreme Court. These were concerning several actions taken by Generics (UK) Ltd trading as Mylan ("Mylan") as well as actions taken by Actavis Group PTC EHF ("Actavis") against Warner-Lambert Company LLC ("Warner-Lambert"). Mylan and Actavis thus wanted the UK part of a European patent belonging to Warner-Lambert to be invalidated as they found it lacking of an inventive step (obviousness) and sufficiency of disclosure. Warner-Lambert had moreover brought an action against Actavis

[202] *Generics v Yeda* (n 199) [36] - [37], [40] - [43], [49] - [50].
[203] ibid [64], [70].
[204] Andrew J K Wells (n 1) 791.
[205] *Generics (UK) LTD (T/A Mylan) v Warner-Lambert Company LLC (Generics v Warner-Lambert)* [2018] UKSC 56, [2018] R.P.C. 21.

and two others as they believed them to have infringed that same patent. The patent concerned a new way of using the pharmaceutical preparation pregabalin. This new use was in the production of a medicament for the treatment of pain and/or the treatment of neuropathic pain, i.e. constituting a swiss-type second medical use claim.[206]

It was foremost in relation to sufficiency that plausibility was actualised at the Supreme Court and, therefore, this part will be examined further. Regarding the "height" of the plausibility threshold, the judges' were of dissenting opinions.[207] However, the majority of the Court agreed with the seven points that Lord Sumption SCJ presented, and these should thus, according to Cronan, form the basis for how plausibility is to be approached in UK patent law. Cronan argues further that these points are also applicable to plausibility in the context of inventive step (obviousness). He defines it as the "Warner-Lambert plausibility test".[208] Wells is of a similar opinion as he argues that even though this case was in relation to a second medical use claim, its core principles should be applicable to other kind of claims as well. This, as the rationale behind it is to prevent speculative patents.[209]

Thus, what Lord Sumption SCJ expressed in the decision of the Supreme Court was that the plausibility test described by Floyd LJ in the decision of the Court of Appeal was set too low; just a little more than a test of good faith. Floyd LJ had stated that the plausibility threshold could be fulfilled by a prediction based on the slimmest of evidence and that T 609/02 *Salk*, therefore did not set out any general principle in that regard. Lord Sumption SCJ disagreed with this statement. He stated that the general principle, set out in T 609/02 *Salk*, is that the patent specification must display some kind of scientific reason for ensuring that the proclaimed therapeutic efficacy in a claim is, in fact, true.[210]

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[206] *Generics v Warner-Lambert* (n 205) [H1] - [H2].
[207] ibid, see e.g. [36] - [37], [180], [193] - [195].
[208] Edward Cronan (n 98) 553.
[209] Andrew J K Wells (n 1) 794.
[210] *Generics v Warner-Lambert* (n 205) [36].

What was considered a bit controversial of some of the other judges was the extent of the burden of proof that Lord Sumption SCJ put on the applicant, as of the statement displayed in the paragraph above. Lord Mance SCJ commented for example that this burden on the applicant was not justified by the case law of the BoA.[211] What the judges agreed on, according to Cronan, is that the burden of proof still lies on the applicant, i.e. positive plausibility. They just did not agree on how much evidence for a therapeutic effect that must be displayed within the patent application (reasonable scientific reason or not).[212]

5.2 Swedish approach

Sweden has, like the UK, ratified the EPC and is closely following the EPO Guidelines and case law of the EPO. Therefore, even though patent infringement procedures (and other post-grant procedures) are conducted on a national level by national courts, the case law of the EPO is still providing guidance to them.[213]

Swedish patent law is regulated through the Swedish Patents Act (Patentlagen). The relevant provision when it comes to inventive step is chapter 1 section 2 of the Swedish Patents Act, which regulates the general patentability requirements. The relevant provision when it comes to sufficiency of disclosure is chapter 1 section 8 of the Swedish Patens Act. In its chapter 7 section 52(1) it is furthermore stated that a granted patent should be invalidated if any of the patentability requirements (inventive step included) is not considered fulfilled. In chapter 7 section 52(2) it is stated that a granted patent should be invalidated if the requirement of sufficiency of disclosure is not fulfilled.

[211] *Generics v Warner-Lambert* (n 205) [180], [193].
[212] Edward Cronan (n 98) 553.
[213] Åsa Andersson, Katarina Söderberg (n 76) 23.

The case law from the Swedish courts displayed below are only from lower courts, since there is, at least to my knowledge, no case law existing yet on plausibility from a higher court. They, thus, do not have the same value as a legal source as the case law from the UK displayed above. This is important to keep in mind through the comparison of the two conducted below[214].

5.2.1 T 258-15 (Actavis v Warner-Lambert)

In this case, from the Stockholm District Court in 2016, plausibility was discussed in relation to invalidation of the Swedish part of a European patent concerning the use of pregabalin in pharmaceuticals for the treatment of pain, belonging to Warner-Lambert Company LLC ("Warner-Lambert") (part of the Pfizer group). Actavis Group PTC ehf. ("Actavis"), a generic medical company, was the claimant. Actavis found the patent lacking an inventive step. Both in relation to prior art and also, more importantly for this essay, in relation to the lack of evidence for the claimed technical effect. The technical effect had, thus, not been made *plausible* according to them. Actavis also made this claim in relation to insufficient disclosure.[215]

The Court examined plausibility in relation to the claimed technical effect under inventive step and sufficiency of disclosure combined, since they found the same facts to be relevant for both examinations. The Court further stated that the examination of plausibility should be based on the application as filed and that Actavis had the burden of proof for stating that the technical effect had not been made plausible.[216]

The Court, when looking at the tests referred to within the patent specification, stated that it was enough that they were referred to for the technical effect to be made plausible. Thus, there was no need for Warner-Lambert to actually conduct those tests or provide any results from them in the patent application. Based on this, the Court found that the technical

[214] See section 5.4.
[215] Stockholms tingsrätt, dom 2016-08-12 i mål 258-15, 1, 8-9, 24.
[216] ibid 54-55.

effect had been made plausible, as it would have been plausible for the person skilled in the art that pregabalin could be used for the treatment of different kinds of pain when looking at the patent application as filed. Actavis had, according to the Court, not been able to prove otherwise and the claim was rejected.[217]

5.2.2 PMT 5263-15 (Actavis v Eli Lilly)

This second case, from the Patent and Market Court in 2017 concerned the invalidation of an SPC since the claimant, Actavis Group PTC ehf. ("Actavis"), believed the patent belonging to Eli Lilly and Company ("Eli Lilly"), concerning the use of atomoxetine in a medicament for the treatment of ADHD, to have been invalid when they applied for the SPC. Actavis thought so as they did not find the patent to fulfil the requirement of inventive step, since it was, firstly, obvious to the skilled person in relation to prior art and secondly (if the Court would not find it to be obvious in relation to prior art) since the claimed technical effect had not been made *plausible* at the priority date.[218]

When developing the claim in relation to the patent not fulfilling the plausibility threshold and thus not involving an inventive step, Actavis referred to the principles set out in T 939/92 *AgrEvo*[219]. They argued that there was no evidence for the claimed technical effect within the patent specification and that the invention was, thus, purely speculative. The post-filed data that was provided to the EPO, on the request of an examiner, should therefore not be taken into consideration when deciding if the technical effect had been made plausible, as it was the very first evidence provided of that effect.[220]

[217] T 258-15 (n 215) 55-56.
[218] Patent- och Marknadsdomstolen vid Stockholms tingsrätt, dom 2017-05-19 i mål 5263-15, 1, 8, 10.
[219] See section 3.2.1 for a detailed description of the case.
[220] PMT 5263-15 (n 218) 20-21.

The Court examined plausibility twice, as there were two different alternatives suggested as the closest prior art by the claimant. In relation to the first alternative prior art the Court stated that, when establishing the objective technical problem, only effects that has been made plausible at the filing date should be taken into consideration. In this regard the Court specifically stated (with a reference to EPO case law) that patents concerning a second medical indication need to contain a description of the chemical compound, making it usable. Moreover, the suitability of utilising the compound for the said treatment should also have been plausibly displayed within the application. The Court, on the other hand, stated that there is no need for clinical results to have been displayed in the application, but there must be some evidence for the technical effect within it in order to allow for the use of post-filed data as evidence as well.[221]

In the patent specification a reference was made to a test, and thus even though there were no tests conducted within the patent specification, the Court found that reference to be sufficient to make the technical effect plausible. Therefore, the post-filed data was also allowed. Since the Court came to this conclusion, also in relation to the other suggested closest prior art, the technical effect was considered to already have been made plausible. The Court, therefore, rejected the claim of Actavis.[222]

5.2.3 PMT 5690-15 (Teva v Boehringer)

This third Swedish case examined, from the Patent and Market Court in 2018, also concerned the invalidation of the Swedish part of an European patent. This patent, belonging to Boehringer Ingelheim Pharma GmbH & Co. KG ("Boehringer"), concerned inhalation capsules with special capsule materials having a reduced moisture content, as well as containing the active substance tiotropium in the form of a powder for an increased stability. Teva Sweden Aktiebolag ("Teva") stated, as the claimant, that the granted patent

[221] PMT 5263-15 (n 218) 45-46, 48.
[222] ibid 49, 52.

was not new in relation to prior art at the filing date and, moreover, that it was lacking an inventive step. Boehringer acknowledged that the patent was partially invalid and, thus, answered with different amended claims, limiting the original patent claims. Teva was thereafter contesting all but one of those amended claims.[223]

It was in relation to the amended claims, principal claims A and B, patent claim 8 that plausibility was actualised. Those changes in claims were namely allowed by the Court and it therefore continued with examining if they fulfilled the requirement of an inventive step in relation to prior art at the effective date of the patent. Teva argued in this regard that there was nothing in the patent making it *plausible* that it actually solved the claimed technical problem it had set out to solve. They therefore argued that Boehringer based the justification of the invention solely on post-filed experimental data, which should not be permitted.[224]

Boehringer, on the other hand, argued that there is no requirement of including experimental data in the original patent application. One should, on the contrary, assume that the claimed technical effect in the patent specification is to be provided, unless there are serious doubts in that regard. The post-filed experimental data was therefore only used as a confirmation of the claimed technical effect.[225]

The Court was referring to EPO case law when stating that inventive step should be examined at the effective date of the patent. This examination should be conducted based on the information in the patent as well as the common general knowledge of the person skilled in the art. With a specific reference to T 1329/04 *John Hopkins* the Court stated that post-filed data could be taken into account when examining inventive step, if the technical effect would already have been held *plausible* for the person skilled in the

[223] Patent- och Marknadsdomstolen vid Stockholms tingsrätt, dom 2018-05-18 i mål 5690-15, 1-4.
[224] ibid 14-15, 22, 28.
[225] ibid 23-24.

art based on their common general knowledge and the patent specification.[226]

However, the Court stated that post-filed data could not be the sole basis for establishing that the claimed technical problem had been solved. The Court found that the patent specification did not make the technical effect plausible and that the post-filed data therefore could not be used by Boehringer for confirming that effect. Thus, the Court found that the principal claims A and B to the patent claim 8, did not involve an inventive step.[227]

5.3 2019 AIPPI World Congress

In 2019 AIPPI discussed plausibility.[228] A Study Question was sent out to its members concerning if plausibility should be considered as an extra patentability requirement. If so, the next question was how its preconditions should be defined. It was stated, as a basis for this question, that plausibility, if considered as a patentability requirement, would generally concern the question if there is sufficient evidence for that the invention's claimed technical effect could actually be achieved. This, as opposed to speculative patent applications. Stakeholders from Sweden and the UK were, among many others, contributing. The results of the Study Question clearly displayed that a majority of all respondents (80%) found it desirable to harmonise plausibility.[229]

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[226] PMT 5690-15 (n 223) 29.
[227] ibid 29, 35.
[228] 'Resolution, 2019 – Study Question – Patents, Plausibility' (*AIPPI World Congress,* London 18 September 2019) <https://static1.squarespace.com/static/5bd185694d546e247ed8971c/t/5db6c63f8ccf9d12e02f36b1/1572259393832/Resolution_Patents_Plausibility_English.pdf> accessed 4 April 2021, 1.
[229] Jonathan P. Osha, Anne Marie Verschuur, Ari Laakkonen, Guillaume Henry, Ralph Nack, Lena Shen, 'Summary Report, 2019 – Study Question – Patents, Plausibility' (*AIPPI,* 2019) <https://aippi.soutron.net/Portal/DownloadImageFile.ashx?objectId=6879> accessed 4 April 2021, 1-2, 4.

Thus, this information can at least be used as an indicator, and a complement to the case law above, of how stakeholders in countries such as Sweden and the UK view the plausibility threshold in order to make a comparison between the two. It is, however, not a legal source and should not be treated as one.

5.3.1 Adopted Resolution

Based on the reports from the national and regional groups (as well as independent members) and the discussion of the topic at the AIPPI World Congress in London in September 2019, a resolution was adopted by the Executive Committee of AIPPI.[230]

It was firstly resolved that there is no need for a stand-alone plausibility requirement, as the creation of one would only lead to legal uncertainty. They furthermore stated in that regard that the patentability and validity requirements existing now, for example inventive step and sufficiency of disclosure, suffice to ensure that the invention, as protected by the claims, is proportionate to its technical contribution defined in the specification, when compared to the state of the art. Therefore, plausibility should only be regarded as one of many elements examined under those already existing requirements.[231]

5.4 Is plausibility applied differently by Swedish and UK courts?

My position is, after having examined the Swedish and UK case law above, that the plausibility threshold has been applied differently between the Swedish and UK courts, but also that the application has varied within those legal systems – depending on the judges view of how the threshold should be applied. A varied application of plausibility is mostly present within the

[230] 'Resolution, 2019 – Study Question – Patents, Plausibility' (n 228) 2.
[231] ibid.

UK courts. They also have a much more developed case law on plausibility than the Swedish ones have (also in higher instance courts, as presented above). Moreover, in the Swedish case T 258-15 (Actavis v Warner-Lambert)[232] one could argue that the plausibility threshold was set very low, as it was enough for making a technical effect plausible that there was a reference in the application to relevant tests. There was no need to provide any results of those tests in the application. This could be compared to the UK case Generics v Warner-Lambert[233] where commentators argue that the decision has set the plausibility threshold quite high[234]. This all is furthermore, in my opinion, proof of general legal uncertainties connected to the application of the plausibility threshold in the post-grant procedure.

As previously displayed[235], national courts do not have to follow the case law of the EPO when making their decisions. It is, however, clear that they do follow it closely, and therefore, in my opinion, there is the need for creating legal certainty regarding the application of the plausibility threshold at the EPO-level as it is currently applied unevenly[236]. The sections below only strengthen this position as they display different legal certainty issues at the national level due to uncertainties created at the EPO.

5.4.1 Varying view of the EPO case law?

Firstly, in Generics v Yeda, Floyd LJ, in the judgment of the Court of Appeal[237], made a division between T 939/92 *AgrEvo* and T 1329/04 *John Hopkins* which is not to be found in any of the other cases above. Floyd LJ namely found them to concern different parts of the inventive step test, where T 1329/04 *John Hopkins* is the case actually concerned with plausibility. Wells agrees with this position, making this kind of division between the two cases as well. The author thus, in relation to the judgment,

[232] See section 5.2.1.
[233] See section 5.1.2.
[234] See more of this under section 5.4.3 below.
[235] See section 2.1.2.
[236] See section 3.3.
[237] See section 5.1.1.

state that T 1329/04 *John Hopkins* concern if the technical effect has been made plausible within the specification, and T 939/92 *AgrEvo* concern if the invention in fact solves the technical problem that is sets out to solve. Even though Wells makes this division he also points out that both tests set out to prevent speculative patents.[238]

The division described in the paragraph above between T 939/92 *AgrEvo* and T 1329/04 *John Hopkins* is in my opinion interesting, even more so as it has not been done in any of the other examined cases. It moreover seems like a concept that has foremost developed within the UK case law, as there is no trace of it in any of the Swedish cases examined. Thus, being evidence of different approaches to the plausibility threshold, as of its unclear scope. It can specifically be connected to the debate previously described[239] concerning the origin of the plausibility threshold, and the different positions as to if T 939/92 *AgrEvo* really concerned plausibility or not.

5.4.2 Combined application of inventive step and sufficiency?

In one of the Swedish cases[240], plausibility was moreover dealt with by the court under inventive step and sufficiency of disclosure combined. This way of combining the two, because of the similar facts being the basis for both evaluations (as the Court argued), were not found in any of the other cases examined. This could potentially be explained by natural causes, namely that the other Swedish cases only concerned plausibility in relation to inventive step. But, in the above examined UK case Generics v Yeda[241] both obviousness (i.e. inventive step) and sufficiency of disclosure was actualised. In this case, however, plausibility was only dealt with by the court in relation to inventive step. This could, in my opinion, be yet another indicator of different national approaches to the concept of plausibility and

[238] Andrew JK Wells (n 1) 787.
[239] See section 3.3.1.
[240] See section 5.2.1.
[241] See section 5.1.1.

how it should be applied. However, this could of course also depend on how the claimant has formulated their claims in the specific case.

5.4.3 Varying approaches in the UK courts

Another interesting aspect, which is touched upon slightly above, is the varying approaches to the plausibility threshold in the different UK courts. A clear example of this is Generics v Warner-Lambert[242] where even the judges within the Supreme Court were of dissenting opinions as to how the plausibility threshold should be applied. Lord Sumption SCJ expressed, for example, that Floyd LJ set the plausibility test too low. That it was basically no more than a test of good faith.

On the other hand, some of the dissenting Supreme Court judges thought that Lord Sumption SCJ put a burden of proof on the applicant that was not in line with the previous case law of the BoA. That instead, it was heightening the plausibility threshold beyond what had been established by the EPO. Cronan also points out that the wording of Lord Sumption SCJ has been generally perceived to raise the plausibility threshold, especially because of the dissenting opinions of Lord Mance SCJ and Lord Hodge SCJ. However, Cronan argues that the position of Lord Sumption SCJ, regarding the requirement of displaying a reasonable scientific reason for the claimed therapeutic effect, might be less burdensome than it seems, as it should be interpreted in the light of the requirement of technical contribution of the invention.[243]

It is in my opinion unclear if the threshold has been heightened or not. Even though Cronan argues that it has not necessarily been heightened through the speech of Lord Sumption SCJ, the worries of Lord Mance SCJ and Lord Hodge SCJ should not be set aside. More case law, or an equivalent

[242] See section 5.1.2.
[243] Edward Cronan (n 98) 552-553.

measure, is therefore necessary for clarifications, both for patent owners and third parties.

5.4.4 Need for a harmonising provision in the EPC?

This question will be elaborated more in chapter 6, but is in my opinion necessary to touch upon under this chapter as well in relation to the resolution of the AIPPI on the topic[244]. As previously stated, this resolution cannot (and should not) be regarded as a legal source. However, it provides some interesting insights into the opinions of legal practitioners and other stakeholders within the relevant field of law in regards to the plausibility threshold. Moreover, the fact that they focused on plausibility during the 2019 World Congress is an indicator of the relevance of the topic as such.

Interestingly, it was resolved that the creation of a harmonising provision would only lead to legal uncertainties[245], the opposite of its purpose. It is, in my opinion, noteworthy that stakeholders had this position, while still acknowledging that there are issues with the application of the plausibility threshold as it is now and the need for harmonising the concept of plausibility. My question is, then, how the harmonisation should be done instead? Perhaps a case from the Enlarged Board would be beneficial for some clarification on the topic? These questions will be further elaborated in section 6.1 and 6.2. below.

[244] See section 5.3.1.
[245] See section 5.3.1.

6 Final discussion

In this chapter the last research question posed will be answered, in the light of the previous analysis conducted in chapters 3, 4 and 5. This question is an overall umbrella question and concern if there is a need for a specific legal provision on plausibility within the EPC, in order to harmonise and tackle any uncertainties regarding the application of the plausibility threshold.

6.1 Is there a need for a specific legal provision on plausibility?

Based on what has been displayed throughout the previous chapters, it is in my opinion clear that there are legal certainty issues regarding the application of the plausibility threshold at the EPO in the pre-grant procedure[246] and, because of these uncertainties, also within national jurisdictions when they apply it in the post-grant procedure[247]. These uncertainties are extra clear and originate specific issues when it comes to broader claims, as has been displayed[248] through the examination of the Markush type claims. This is problematic as these uncertainties affect applicants, patent owners and third parties in the pharmaceutical sector. It furthermore affects the fundamental goal of the patent system, as legal certainty is crucial for the system to properly work as incentives for innovation.

It has previously been shortly discussed[249] if there is a need for a harmonising provision within the EPC, as the stakeholders behind the AIPPI resolution in 2019 were not of such an opinion. Even though, they found the

[246] See section 3.3.
[247] See section 5.4.
[248] See section 4.2.
[249] See section 5.4.5.

harmonisation of plausibility to be a necessity. There is, also in my opinion, a strong need to harmonise the plausibility threshold in order to tackle the uncertainties regarding its application. However, how it should be done is less certain. As stated above[250] national courts do not have to follow the case law of the EPO when deciding in post-grant procedures. Although, in my opinion it has been made clear[251] that both of the examined national jurisdictions have adjusted their national legislation in line with the EPC and their courts clearly follow the case law of the EPO. This evidently indicates the influence that EPO, through its case law and the EPC, has over national jurisdictions.

A problem connected to the creation of a provision on plausibility in the EPC is how to formulate it in an unambiguous way. If it would not be clearly formulated the risk is, as expressed by the members of the AIPPI[252], that it would only create legal uncertainties and, thus, go against its own purpose. But, on the other hand, as the application of plausibility is currently done unevenly both at the EPO[253] and national level[254] the creation of a provision could in my opinion be a fundamental first step for an even application of plausibility in the pre-grant procedure, and subsequently for an even application in the post-grant procedure as well.

Necessary criterias to have in such a provision would, based on the issued discussed in the previous chapters, be (1) a general notion of the amount of verifiable or experimental data the applicant need to provide within the application, as well as its character or quality in order to reach the plausibility threshold and (2) the amount of compounds within the claim that the applicant has to prove (make plausible) are working, e.g. "substantially all" like in T 939/92 AgrEvo[255]. It is however important that such a provision would not set the plausibility threshold too high or too low,

[250] See section 2.1.2.
[251] See chapter 5.
[252] See section 5.4.5.
[253] See chapter 3.
[254] See chapter 5.
[255] See section 3.1.1.

as that would only risk hindering innovation. Thus, in order for the provision to work with the fundamental purpose of the patent system - to provide incentives for innovation - it must moreover offer some flexibility. This is particularly important within the pharmaceutical sector, as displayed above[256]. My overall position is that if it is possible to create such a harmonising provision within the EPC, without making it ambiguous, it could be a good solution in order to tackle the uncertainties connected to it. Especially since national jurisdictions adjust their national patent laws after the EPC.

6.2 Other necessary measures?

In my opinion, another solution could be to develop the EPO Guidelines on the topic of plausibility in order to clarify the position of the EPO in that regard. Moreover, for this, a case from the Enlarged Board could be a necessary first step to create some clarity as, what have also been previously displayed[257], they provide guidance in legal topics of fundamental importance, for example when two BoA have given decisions with different outcomes on the same legal topic.

As my position is that plausibility has proven to be a legal topic of fundamental importance, that has been applied unevenly by the Boards, this step could be essential. There are, however, advantages and disadvantages to this approach. One could assume that a case from the Enlarged Board would be a faster and more flexible way of creating some clarification on the plausibility issue than to formulate a precise enough legal provision within the EPC. But, on the other hand, a precise enough provision could provide more overall guidance, and thus legal certainty, on the application of the plausibility threshold than a case that still depend on, and is adapted to, its specific circumstances. However, the usage of one of these measures does of course not exclude the possibility to use any of the other ones as well. A combination of measures could be beneficial.

[256] See section 4.2.3.
[257] See section 2.1.2.

7 Conclusion

There is an uneven application of the plausibility threshold at the EPO as well as in and between different national jurisdictions in relation to pharmaceutical patents, resulting in legal uncertainties for applicants, patent owners and third parties. These uncertainties become extra clear, and originate specific issues, in relation to broad claims such as Markush type claims as their technical effect is already difficult to prove due to their complexity. The Markush type claims are however important for the pharmaceutical sector and an uncertain application of the plausibility threshold, or a threshold that is set to high or too low, thus, risk hinder innovation within this sector as inventors might hesitate in filing for patents. There is therefore the need for a harmonising measure in order to tackle the uncertainties that are connected to the application of the plausibility threshold. A provision within the EPC on plausibility could in my opinion be a good solution to this problem, but only if it can be formulated in an unambiguous way. Otherwise it only risk creating even more uncertainties.

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