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Biopatent Law: European vs. US Patent Law

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Preface

Patents protecting biotechnological invention become ever more important. Because Biotechnology has many differences with respect to other technologies, lessons learned in other fields of technology cannot simply be transferred to adopt a suitable strategy for dealing with Biotechnology inventions.

In this issue, legal aspects of biotech patents will be discussed. This involves questions of biopatent prosecution, including novelty, inventive step, written disclosure and sufficiency of enablement, as well as questions of law enforcement of biotech patents. Another issue are particular aspects of US patent law, which can have tremendous differences compared to European law.

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Patentability Requirements of Biotech Patents

Ulrich Storz

Abstract This chapter discusses patentability requirements in the two major patent jurisdictions, namely novelty, non-obviousness/inventive step, enablement/written description, best mode, and sufficiency of disclosure. Differences between Europe and the United States are highlighted, and practical implications are discussed with respect to the biopatent field.

Keywords Novelty · Obviousness · Enablement · Written description · Best mode · Industrial applicability · Inventive step · Sufficiency of disclosure · Biotech

1 Introduction

As discussed earlier in this book series, the allowance of a patent is subject to substantial examination. During this process, a number of tests is carried out, part of which are similar in the major patent jurisdictions, while others differ from one another substantially.

In the US patent system, the United States Code, Section 35 (USC 35) is decisive, whereas in the European patent system, the European Patent Convention (EPC) sets the standards. The following list gives an overview of the patentability requirements under USC 35 and EPC.

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USC 35		EPC	
Requirement	Legal basis	Requirement	Legal basis
Novelty	§ 102	Novelty	Art. 54
Non-obviousness	§ 103	Inventive step	Art. 56
Enablement requirement	§ 112	Sufficiency of disclosure	Art. 83
Written description requirement	§ 112		
Best mode	§ 112		
		Industrial applicability and exclusion of methods of treatment and diagnosis	Art. 57, Art. 53 (c)

The present chapter will focus on a comparison of the tests as to novelty as carried out by the USPTO and the EPO to patents from the biotechnology discipline. Before doing so, however, some requirements specific to the two jurisdictions will be shortly addressed.

2 Foreplay: Requirements Specific to Either the EPC or USC 35

2.1 Industrial Application (Art. 57 EPC) and Exclusion of Methods of Treatment and Diagnosis (Art. 53 (c) EPC)

The test on industrial application as applied under Art. 57 EPC was initially used to block inventions which were related to therapeutic and diagnostic methods. The ratio behind this ban is that medical practitioners should not care about patents when deciding about practicing a given method of therapy or diagnosis. The industrial application standard is derived from the fact that, in Europe, medical professions are not considered to qualify as "industrial" or commercial. The exclusion of methods of treatment and diagnosis of humans and animals is furthermore specifically codified in Art. 53 (c) EPC.

2.1.1 Compound Patents Which Suffer from Insufficient Disclosure

Recently, Art. 57 has been used to block therapeutic compound patents which were filed at a stage where the applicant had no idea of the potential therapeutic use yet. Decision T870/04, which related to a patent application encompassing the hematopoietic cytokine receptor, and therapeutic antibodies binding thereto set forth that

> the mere fact that a substance can be made in some way does not necessarily mean that Art. 57 EPC is fulfilled, unless there is also some profitable use for which the substance can be employed.

However, this bar is very low. Technical Board's decision T0018/09 made this clear. The underlying patent EP0939804 assigned to HGS related to nucleic acids encoding for Neutrokine-α and an antibody that binds specifically to Neutrokine-α (now: BLyS or BAFF). Neutrokine-α is a member of the TNF-α superfamily, and was novel at the time of filing, but no experimental data were given as to therapeutic use, nor was a real antibody made. The applicant had only provided tissue distribution experiments of Neutrokine-α mRNA).

Nonetheless, the board judged that tissue distribution data suffice for industrial application and may be used to develop appropriate means for diagnosis and treatment. The key statement reflecting the board's opinion was as follows:

> In the board's judgment, the tissue distribution of Neutrokine-α mRNA disclosed in the patent-in-suit, in particular the expression of Neutrokine-α mRNA in B cell and T-cell lymphomas (…), provides in itself in the context of the disclosure a valid basis for an industrial application. The presence of Neutrokine-α in these lymphomas 8…] may be used to develop appropriate means and methods for their diagnosis and treatment based on the disclosure of the patent-in-suit.

The patent was thus maintained.

In corresponding proceedings in the UK, the Court of Appeal found the patent invalid for lack of industrial applicability, insufficiency, and obviousness, but the Supreme Court overturned this view, re-established industrial application and remanded the case. The Court of Appeal then established validity on September 5, 2012.

This decision thus defines the bottom line of real-world evidence applicants need today to meet the industrial application requirement in case they want to protect a new therapeutic compound. It is thus fair to say that, in today's examination policy, the industrial application requirement is easily met and has a practical role only when it comes to methods of treatment and diagnosis.

2.1.2 Medical Use Claims

Inventions that relate to a new indication for a pharmaceutical drug suffer from a conceptual problem, because, on paper, they relate to the use of said drug for a medical purpose and, as such, to a method of treatment which is exempt from patent protection under Art. 53 (c) EPC.

Under the last version of the EPC ("EPC 1973"), so-called Swiss-type claims were the only acceptable form of claiming a second medical use, because only under this wording an exclusion under then Art. 52 (4) EPC (now Art. 53 (c)) could be avoided. The Swiss-type claim language, which claimed the "Use of compound X in the manufacture of medicament Y for treatment of disease Z," was established by the Enlarged Board of Appeal (EBA) of the EPO in decision G5/83.

This format was a mere auxiliary construct to provide a commercial character to what otherwise would have been considered a mere therapeutic treatment. In decision G5/83, the EBA derived the novelty of such claims from their sole new feature, that is, the new pharmaceutical use of that known substance. The passage "in the manufacture of medicament," which is a common feature of all Swiss-type claims, was, however, never considered to have a restricting character. In fact, the scope of Swiss-type claims has always been defined as "purpose-bound compound protection."

Swiss-type claims are obsolete under the revised EPC (also called EPC 2000) and no longer allowable according to EBA decision G2/08, because the new Art. 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses.

The board stated that

> Article 54(5) EPC now permits purpose-related product protection for any further specific use of a known medicament in a method of therapy. Therefore, […] the loophole existing in the provisions of the EPC 1973 was closed. In other words "cessante ratione legis, cessat et ipsa lex", when the reason of the law ceases, the law itself ceases.

However, not only the necessity of using the Swiss-type format has ceased. The board also found them unallowable for future applications:

> Therefore, where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G5/83.

The Swiss-type claim wording is today, replaced by a true second medical use wording, e.g., "Use of compound X for treatment of disease Z." As regards the scope of protection, this change has formal character only, because even before, Swiss-type claims were true medical use claims.

In the United States, such claim wording is not accepted, as "use" is not a claim category as provided by the US Patent Act.[1] Therefore, the corresponding claim wording should be as follows: "A process comprising administering a composition comprising compound X to a human in an amount effective for treating a disease Z".

2.2 Sufficiency of Disclosure (Art. 83 EPC)

2.2.1 General Issues

According to Art. 83 EPC, the application must disclose the invention sufficiently clear and complete to be carried out by a person skilled in the art. Case law

[1] 35 USC § 101: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a Patent therefore."

interprets this requirement in a straightforward way. Technical Board's decision T94/82, for example, claims that

> The description must enable the person skilled in the art to obtain the claimed product described in it.

Technical Board's decision T0609/02 states that

> If the description […] provides no more than a vague indication of a possible medical use […], later more detailed evidence cannot be used to remedy the fundamental insufficiency of disclosure of such subject-matter.

The decision went on by stating that

> a simple verbal statement in a patent specification that compound X may be used to treat disease Y is enough to ensure sufficiency of disclosure […]. It is required that the patent provides some information in the form of, for example, experimental tests, to the avail that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.

In like manner, Technical Board's decision T1329/04 stipulates that

> [t]he definition of an invention as being a contribution to the art, i.e., as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve.

One may from these decisions conclude that there is a disclosure requirement under the EPC, but it seems that the height of the respective bar changes from case to case.

2.2.2 Degree of Generalization and Non-working Examples

The disclosure requirement strives to ensure that a skilled person can reproduce the subject matter of the invention without undue burden. EPO examiners apply a quite liberal policy with respect to patent claims which comprise a generalized subject matter, provided the latter is novel, and a working example has been disclosed that falls under the scope thereof.

One example is thus usually sufficient to provide enablement, as long as no evidence exists that embodiments falling under the scope of the patent are not enabled. Accordingly, the guidelines for examination, which describe the general outlines of the EPO examination policy, set forth in Chapter F. IV that

> A claim in generic form […], may be acceptable even if of broad scope, if there is fair support in the description and there is **no reason to suppose that the invention cannot be worked through the whole of the field claimed**.

At the same time, the guidelines set forth that an examiner should

> raise an objection of lack of support only if he has well-founded reasons. Once the examiner has set out a reasoned case that, for example, **a broad claim is not supported over the whole of its breadth**, the onus of demonstrating that the claim is fully supported lies with the applicant Where an objection is raised, the reasons should, where possible, be supported specifically by a published document.

Thus, in case evidence exists that a patent claim is not supported over the whole of its breadth—in other words, a non-working example—the patent examiner may decide to narrow the scope of the claims to the very embodiment for which enabling data have been presented.

Such approach is oftentimes used by third parties, who file observations in the ongoing prosecution, or lodge an opposition, on the basis of a non-working example that also falls under the scope of said claim. It is in the nature of the examination process as such that these objections will mostly be raised by third parties, i.e., competitors, rather than by examiners, who have, generally speaking, no ambition to find non-working examples from literature, their search focus being directed at issues of novelty and inventive step.

One example for the increasing scrutiny with respect to sufficient enablement is given in Technical Board's decision T0601/05, which is related to a first-generation patent claiming human monoclonal antibodies (mAbs) that bind to human tumor necrosis factor α (TNF-α). The only method for the production of the claimed antibodies disclosed in the patent was the hybridoma technique developed by Köhler and Milstein (1975). In opposition proceedings, the board came to the conclusion that the hybridoma technique would not be suited to prepare high-affinity antibodies against TNF-α:

> Accordingly, human peripheral blood cells from a normal healthy individual cannot provide a route to high-affinity, neutralising antibodies to TNF. Thus, in the light of the evidence summarized above, the board is convinced that the method disclosed in the patent, even if combined with common general knowledge relating to this method, does not enable the skilled person to produce antibodies binding with high affinity to soluble TNF.

Because the claim language encompassed both high-affinity, neutralizing antibodies against self-antigens and low-affinity antibodies, the claim was found to be not sufficiently enabled by the specification.

The broadness of a given claim is thus limited not only by the prior art, but also by the existence of non-working examples falling thereunder.

2.3 Enablement and Written Description Requirement (USC 35; § 112)

Sufficiency of enablement and written description are two requirements under USC 35; § 112 which have often been mixed up even by patent professionals.

In March 2010, the US Court of Appeals for the Federal Circuit ("CAFC") issued a decision in case *Ariad vs. Eli Lilly*[2] which made clear that § 112 contains both (1) a written description requirement and (2) an enablement requirement and that both requirements differ from one another. Following this ruling, a patent specification

1. must describe the invention sufficiently so that one of the ordinary skills in the art would understand that the inventor possessed the subject matter claimed and ("written description requirement")
2. must teach one of the ordinary skills in the art how to make and use the invention ("enablement requirement")

The underlying case was related to Ariad's patent US6410516, which dealt with transcription factor NF-κB, and methods of reducing or altering its activity, yet without indicating how this could actually be done. The patent contained broad genus claims covering the use of all substances that achieve the desired result of inhibiting NF-κB activity. Although the specification recited the desired goal of reducing NF-κB activity, it did not disclose any working or even prophetic examples of methods that reduce NF-κB activity, and no completed syntheses of any of the molecules prophesized to be capable of reducing NF-κB activity.

In their request for *en banc* rehearing, Ariad claimed that there is no separate written description requirement in § 112, but that the description is just to identify what needs to be enabled. The CAFC rebutted this allegation by stating that:

> If Congress had intended enablement to be the sole description requirement of § 112, first paragraph, the statute would have been written differently.

The CAFC further noted that, in order to meet the written description requirement, more than merely repeating claim language in the specification is necessary:

> Generic claim language appearing in ipsis verbis in the original specification does not satisfy the written description requirement if it fails to support the scope of the genus claimed.

The court then specified what degree of evidence is required to meet the description requirement:

> The test requires an objective inquiry into **the four corners of the specification** from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must […] show that the inventor actually invented the invention claimed.

The patent was thus found invalid for failure to meet the written description requirement. The decision fuels fears that the written description requirement discriminates against universities and start-up ventures that have their emphasis in basic research. These entities are under constant pressure to secure their results at the earliest possible date, and to the broadest possible extent, in order to publish

[2] 598 F.3d 1336, 1341 (Fed. Cir. 2010).

them or present them to potential licensees. A requirement for additional data in the future will increase the financial burden for these small or non-commercial entities.

In another groundbreaking case (*Centocor vs. Abbott*[3]), Centocor sued Abbott for patent infringement by selling adalimumab (Humira). Basis for the legal action was Centocor's patent US7070775, which relates to human antibodies to human TNF-α. The '775 patent is a continuation in part (CIP) of an earlier application by Centocor, which was related to chimeric antibodies.

However, said earlier patent predated a patent by Abbott related to similar subject matter. The case had generated broad public interest due to a record verdict in the first instance under which Abbott was sentenced to pay $1.67 bn in damages. On appeal, the decision was fully reversed by the CAFC only for lack of written description.

The CAFC considered that most claims of the '775 patent lacked written description, because the specification did not describe the claimed human antibody, nor an antibody with a human variable region, and concluded that

> "the scope of Centocor's right to exclude cannot over-reach the scope of its contribution to the field of art as described in the patent specification".

The claims on which Abbott had been sued were thus declared invalid.

Thus, while written description and enablement are not the same, the former focuses on the question whether the invention is described in such a way that the skilled person would understand that the inventor actually **possessed the invention**, while the latter relates to whether the invention is taught in such a way that the skilled person understands **how to make and use the invention**, both are important requirements, and should be considered with care, especially in cases where an application is meant to be filed at a very early stage, e.g., in order to secure an early priority date.

2.4 Best Mode (USC 35; § 112)

The recent amendment of US patent law under the America Invents Act (AIA), which went into effect on March 16, 2013, brought with it a removal of the so-called best mode requirement from the list of possible invalidity defenses.

The best mode requirement was considered a safeguard against the desire on the part of some people to obtain patent protection without making a full disclosure as required by the statute. This means that inventors were not allowed to disclose only what they knew to be their second-best embodiment, while retaining the best for themselves. The best mode requirement thus faithfully reflects basis principles of patent law, namely "quid pro quo" and "duty of candor and good faith."

In *Glaxo vs. Novopharm*,[4] the CAFC explained the essence of the best mode requirement as follows:

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[3] 2010-1144 CAFC.

[4] 52 F.3d 1043, 1050 (Fed. Cir. 1995).

> The sole purpose of the best mode requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived. The best mode inquiry focuses on the inventor's state of mind at the time he filed his application […] The specificity of disclosure required to comply with the best mode requirement must be determined by the knowledge of facts within the possession of the inventor at the time of filing the application.

Further, the CAFC provided a comparison between best mode and enablement:

> Enablement looks to placing the subject matter of the claims generally in the possession of the public. Best mode looks to whether specific instrumentalities and techniques have been developed by the inventor and known to him at the time of filing as the best way of carrying out the invention. The **enablement requirement**, thus, looks to the **objective knowledge of one of ordinary skill in the art**, while the **best mode** inquiry is a subjective, factual one, looking to the **state of the mind of the inventor**.

As already envisaged, failure to disclose the best mode was removed, under the AIA, from the list of possible invalidity defenses to an infringement action. Further, failure to meet the best mode requirement will no longer be a factor in determining the priority date of a claim.

The USPTO has, however, advised examiners that objections addressing best mode requirement can still be raised during prosecution. The best mode requirement is thus still a very important requirement to meet.

3 Novelty and Inventive Step/Non-Obviousness: The Moving Target

The biotechnology disciplines underwent substantial advancements in the past 20 years. In antibody engineering and design, for example, the quick progress included the development of recombinant chimerization and humanization techniques, and the creation of libraries, display methods, and affinity maturation approaches. However, in a global knowledge society, a method that was cutting-edge technology yesterday may be an industry standard today, particularly with respect to technical disciplines that are strongly influenced by academic research. This is particularly true for biotechnology.

This situation is reflected in the increasing scrutiny patent authorities exhibit, e.g., with respect to antibody-related patent applications. The hurdles are steadily set higher, or, as the European Patent Office (EPO) puts it, "the bars are raised."

3.1 Novelty

Contrary to increasing requirements as to inventive step/non-obviousness, the respective authorities, including the EPO and the USPTO, seem to have recently

lowered hurdles with respect to the novelty requirement at least in some aspects. In others, the novelty bar has been raised, as will be discussed in the following.

3.1.1 Selection Inventions

Recent case law related to small molecules has strengthened the concept of selection inventions, which is established granting practice at the EPO already and which stipulates that the disclosure of a chemical class does not necessarily anticipate the novelty of an individual compound falling within this class. This is the so-called genus-species anticipation, according to which "a species anticipates the genus, whereas the genus does not anticipate a species".
This means, for example, that despite the fact that the racemate of a given structure is prior art, a patent related to only one enantiomer of said racemate may be considered novel and thus patentable in case the inventive step requirement is met (e.g., due to difficult resolution of the racemate). This view has been consented by courts in the UK, Germany, and the USA with respect to the (+)-enantiomer of Citalopram (decisions *Generics UK vs. Daichi*,[5] *BGH Escitalopram*,[6] and *Forest Labs., Inc. vs. Ivax Pharm., Inc.*).[7]

In another example, courts in all three countries agreed that a given compound, which falls within the scope of a general formula disclosed in the prior art, can be considered novel if it is not mentioned explicitly in the latter, but only by means of a Markush group in which some substituents are designated as R1–RX. Courts in UK, Germany, and the USA came to similar results in cases related to the anti-psychotic olanzapine (decisions *Dr. Reddy's vs. Eli Lilly*,[8] *BGH Olanzapin*,[9] and *Eli Lilly & Co. vs. Zenith Goldline Pharm., Inc.*).[10]

Translated to biomolecules, this means that, e.g., a sequence claim related to a second-generation antibody will be considered novel even if said claimed sequence is comprised in the similarity interval of a prior sequence disclosure (e.g., "SEQ ID No 1, or sequences having a similarity of >95 % with the former").

3.1.2 The Problem of Prior Art Applications Which are Post-published

According to a general principle, an invention is deemed novel if it is not known from the state of the art. The state of the art is composed of everything made

[5] (2008) EWHC 2413 (Pat), 2008 Bailii EWHC 2413.
[6] Xa ZR 130/07 (BPatG), 2009, GRUR 2010, 123.
[7] 501 F.3d 1263 (Fed. Cir. 2007).
[8] (2008) EWHC 2345 (Pat), 2008 Bailii EWHC 2345.
[9] Olanzapin, X ZR 89/07 (BPatG) 2008, GRUR 2009, 382.
[10] 05-1396, 05-1429, 05-1430, 2007 U.S. App. LEXIS 8750.

available to the public, e.g., by means of written description, before the priority date of a patent application.

Quite understandably, prior patent literature forms part of the state of the art, like any other type of literature. However, in most jurisdictions, patent applications are only made available to the public 18 months after their priority date. This can lead to a situation where, at the priority date of a given patent application ("application 2"), an earlier-filed patent application assigned to a third party exists already ("application 1"), which discloses similar or identical subject matter, but has not yet been published, and was thus unknown to the inventor of application 2. At the time of filing, the latter had thus reason to believe that his invention was novel—which it in fact was taking the above standard of availability to the public as a measure.

However, such constellation could lead to a situation in which the inventor of application 2 could obtain a patent on an invention that has already been described earlier in application 1 and assigned to another inventor.

In order to account for this problem, which could lead to double patenting, Art. 54 (3) EPC stipulates that the content of European patent applications filed prior to a given patent application, but published after the priority date of the latter, shall be considered as comprised in the state of the art.

Because of the fact that avoidance of double protection is the driving force behind this exception, its scope is restricted to assessment of novelty. Hence, under Art. 56 EPC such type of document (termed Art. 54 (3) document) shall not be considered in deciding whether the latter application relies on an inventive step. Thus, Art. 54 (3) EPC only applies for earlier-filed, yet post-published European patent applications (including PCT applications, provided they have been filed in an official language of the EPO), and prior art made available under this regulation can only be used for novelty objections.

Under the AIA, a similar regulation was recently introduced into US patent law. Contrary to the European regulation, however, the exception (1) applies to earlier-filed patent applications from any country and (2) prior art made available thereunder can be used for novelty objections and obviousness objections, again provided the alleged prior art document is subsequently published.

3.2 Inventive Step/Non-Obviousness

Probably due to the rapid technological progress in the biotechnology industry, arguments that were accepted in support of sufficient inventiveness in the past now may be rejected by the patent authorities as falling under the routine of a skilled artisan.

In view of the fact that technologies for the production of a human antibody against a given target are now state of the art (consider, e.g., native antibody libraries and phage display), the mere provision of a human antibody against a target the clinical implications of which are known would have difficulties to meet

the inventive step/non-obviousness requirement. In other words: The biotech industry is, in some way, a victim of its own success.

The test on inventive step, or non-obviousness, differs from the novelty test, in that an invention that passes the novelty test may still be objected as lacking inventive step, or being obvious, over the prior art. The ratio behind it is that embodiments may exist which, although formally novel, do not deserve exclusivity because they rely on a mere routine combination of features from the prior art, without any surprising effect or benefit emanating from that new combination.

Needless to say that such test is subject to large variances, because it suffers from conceptual problems, including subjectiveness, hindsight, and even language issues.

In order to anticipate obviousness objections during patent prosecution, applicants should add, to their applications, fallback positions, and experimental data, which can be used as a last resort to obtain patent protection for the actual compound or technology. Further, most of these data may also be used to meet the written description and enablement requirement (see above).

3.2.1 The European Approach

The test the EPO routinely applies is the so-called problem–solution approach, which follows a strictly predetermined line. The EPO has established this approach in an attempt to increase the degree of reproducibility in questions of inventive step (which otherwise would be subject to high variability, particularly in a trilingual system).

The approach consists of four steps:

1. Identify "closest prior art" (usually the prior art document which has most features in common with claimed subject matter) and determine the lacking features (the "delta")
2. determine the "objective technical effect" which said "delta" has
3. determine the "objective technical problem"—which is merely to achieve the objective technical effect starting from the closest prior art
4. "Could-Would test": Would (not only could) a skilled person in charge of solving the objective technical problem have come to the claimed solution by combination of the closest prior art document with another prior art document?

The "Could-Would test" thus seeks to determine whether, beyond the mere theoretical possibility that when combining two prior art documents one would have arrived at the claimed solution, a skilled person would actually have done so.

In Biotech, the preferred "Could-Would test" is the "Reasonable expectation of Success" test.

Practically, the problem–solution approach allows successful obviousness attacks only in case the "delta" between the claimed subject matter and the closest prior art is small, which means the latter must not lack more than one feature.

3.2.2 The US Approach

Under US law, the key features of the non-obviousness test have been laid out by the US Supreme Court in *KSR vs. Teleflex.*[11] In said decision, the court made, inter alia, the following statements:

> Obviousness requires more than a mere showing that the prior art includes separate references covering each separate limitation in a claim under examination.
>
> Rather, obviousness requires the additional showing that a person of ordinary skill at the time of the invention would have selected and combined those prior art elements in the normal course of research and development to yield the claimed invention.
>
> A person of ordinary skill at the time of the invention interprets the prior art using common sense and appropriate perspective.

The Supreme Court overturned an earlier decision by the CAFC and found that the latter had applied the so-called teaching-suggestion-motivation test (TSM) test in an overly rigid and formalistic way.

The Supreme Court made clear that, under the TSM test, a claimed invention is obvious when there is a teaching, suggestion, or motivation to combine prior art teachings. The teaching, suggestion, or motivation may be found in the prior art, in the nature of the problem, or in the knowledge of a person having ordinary skill in the art. The court, however, set forth that the TSM test is not the only rationale that may be relied upon to support a conclusion of obviousness.

In the earlier decision *Graham vs. John Deere*,[12] the Supreme Court had already defined the so-called Graham factors, according to which obviousness should be determined by looking at

1. the scope and content of the prior art;
2. the level of ordinary skill in the art;
3. the differences between the claimed invention and the prior art; and
4. objective evidence of non-obviousness

The latter are, for example, commercial success, long-felt but unsolved needs, and failure of others.

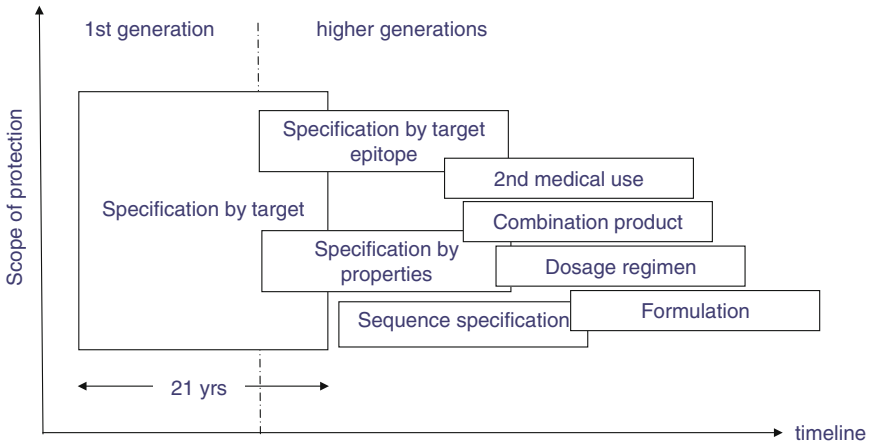
While the basic outline of these approaches shares some similarity with the problem–solution approach used by the EPO, there is the general perception that the latter is more formalistic, giving the examiners less room for interpretation. Further, under the problem–solution approach, an inventive step attack based on a combination of more than two prior art documents is unlikely to be successful, while USPTO examiners regularly object patent applications for obviousness in view of a combination of three or more prior art documents.

[11] 550 U.S. 398, 418 (2007).

[12] 383 U.S. 1 (1966).

3.2.3 The Situation in Therapeutic Antibodies

In therapeutic antibodies, which are one of the commercial success stories in biotechnology, different patent generations can be determined, all being derivatives of a first patent application which has a claim on a theoretical antibody against a new target. The following figure shows the most important categories of patent protection in therapeutics antibodies. Note that the units are arbitrary, and the actual order of the different categories may vary from case to case. Further, note that not in each case all categories are used.



Among these different types of protection, specification by target and specification by sequence are probably the two most important types. We will discuss inventive step issues with respect to these two categories in the following:

mAb Specification by Target: Background

Today, about 100 cellular targets are addressed by approved biopharmaceuticals, yet the spectrum of promising targets for new therapeutic mAbs is much higher (Overington et al. 2006). There is thus still room for the discovery of a new target and for the invention of a drug addressing said target.

In case an applicant specifies a new target in sufficient manner, and renders plausible a therapeutic effect of blocking said target, the EPO accepts claims related to a theoretical mAb against said target ("target claims"), even if the applicant has never actually made such mAb, or only made a polyclonal or murine monoclonal.

This position is, for example, demonstrated in Technical Board's decision T542/95, which related to antibodies against human TNF. The board argued that

> The prior art does not disclose the purification of the same hTNF (CT) as in the patent in suit. […]. Accordingly, the **presence of inventive step can be acknowledged** for the claims.

Contrary to USC 35; § 112, the EPC has no explicit written description requirement, and thus, "possession of the invention" is not a statutory requirement. EPO's ratio is that the skilled person has, by specifying the target, enabled the skilled person to make an antibody against said target by routine methods (Koehler Milstein, Phage display etc.). Therefore, it is considered a fair reward for the applicant of protein X to be granted a claim related to a theoretical antibody against said protein.

mAb Specification by Sequence: Background

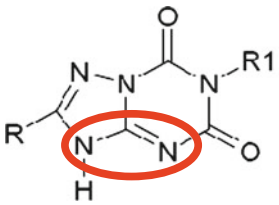
Another way to create patent protection for a second- or higher-generation antibody is to specify a sequence thereof ("sequence claims"). The scope of protection of such claim type is, on paper, pretty narrow, and issues of equivalence are so far unresolved, as no case law exists yet with respect to scope of equivalence of biosequence claims.

However, the European Medicines Agency (EMA) will most probably consider counterfeit products only as biosimilars (and thus eligible for facilitated approval) in case of an identical amino acid sequence. Thus, even if the scope of protection of an antibody sequence claim could be bypassed by exchanging one amino acid only, such approach is no option for biosimilar companies who want to take benefit from facilitated approval pathways. These companies thus have to wait until the patent expires. Thus, although theoretically narrow, structural claims can provide meaningful and strong protection for an approved antibody.

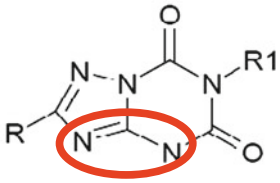
In antibody sequence claims, the EPO usually requires at least two variable chains (heavy and light), or all six CDRs to be recited in the claim. The ratio behind this requirement is that at least six CDRs, or the heavy and light chain, are needed for proper binding function. For single-domain antibodies or binding peptides, less can be sufficient if experimental evidence is provided.

In structural small molecule claims, it is established EPO case law that novelty more or less implies that the inventive step criterion is also met. Only in case a structurally similar molecule is prior art, and it was predictable that the modification which is subject to the patent has no negative effects, the EPO requires a "surprising effect" to meet the inventive step criterion.

For example, the following two compounds are not considered to be "structurally close," because of differences in the heterocyclic system:



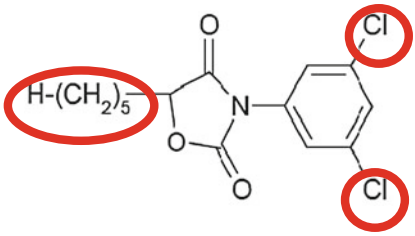
1A (prior art)



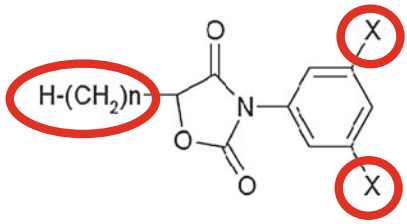
1B (novel)

Because both compounds are not structurally close, the EPO does not require compound 1B to exhibit advantages or surprising effects over compound 1A for being considered as being based on an inventive step.

In contrast thereto, the following two compounds are considered to be "structurally close," because the two ring systems are essentially the same.



2A (prior art)

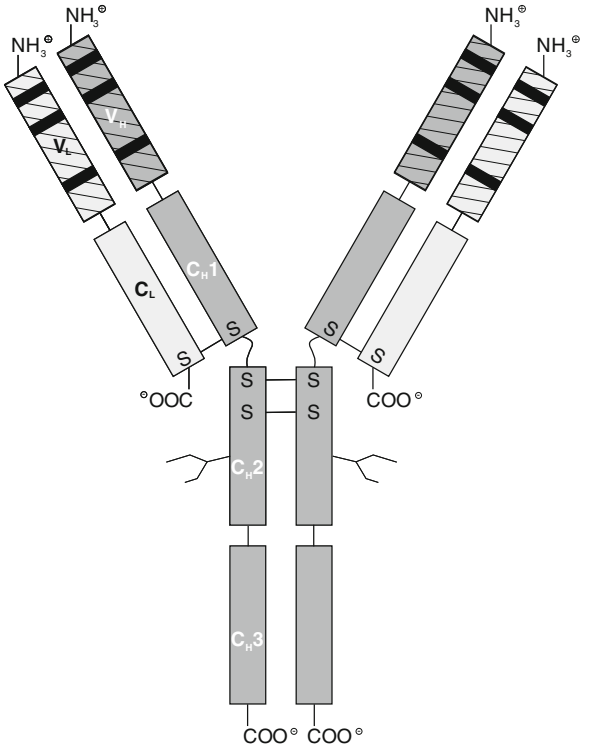


2B (novel), n = 2, 3

Hence, compound 2B has to exhibit advantages or surprising effects over those exhibited by compound 2A for being considered as non-obvious.

In contrast thereto, the EPO regularly requires, in structural antibody claims, that the applicant provides "surprising effects" over existing antibodies against the same target. Following an analogy to the examination policy in small molecules, the EPO stipulates that all IgG are "structurally similar," because they share the same backbone, in which, essentially, only the complementarity determining regions (CDRs) have been replaced according to the respective target.

The latter form, however, only a very small fraction of the entire structure of, e.g., an IgG antibody, as can be seen in the following figure (black bars show the CDRs):



The provision of "yet another antibody" against a known target is considered to be in the routine of the skilled person, because respective methods exist (phage display, affinity maturation, and the like). The EPO thus considers structural antibody claims which address a target already addressed by earlier antibodies as not inventive unless surprising effects are disclosed by the applicant—a policy which has been termed the "antibody sonderweg".

This position is, nowadays, established case law. In Technical Board's decision T512/94, the respective board states that

> Once a monoclonal antibody with essentially the same properties as desired had been isolated, the skilled person would consider the **isolation of another equivalent antibody as reasonably feasible**, if only by following the very same method.

In Technical Board's decision T735/00, the board concluded that

> If, however, there are no **unexpected effects achieved with a further monoclonal antibody** compared with a monoclonal antibody with essentially the same properties as desired the case law denies inventive step.

In Technical Board's decision T 735/00, the board had to decide about, inter alia, on the inventive step of the following claim:

> 1. A monoclonal antibody selected from the group consisting of monoclonal antibody CRP-1 obtained from hybridoma cell line CRP-1 (FERM BP-2873), monoclonal antibody CRP-2 obtained from hybridoma cell line CRP-2 (FERM BP-2874), monoclonal antibody CRP-3 obtained from hybridoma cell line CRP-3 (FERM BP-2875), and monoclonal antibody CRP-4 obtained from hybridoma cell line CRP-4 (FERM BP-2876).

The closest prior art disclosed two antibodies against CRP. The board came to the conclusion that the technical problem was to find an alternative mAb against CRP. Yet, 13 years after Köhler and Milstein, the board saw no merits in using this method to make an alternative antiCRP-mAb in the absence of any unexpected properties and revoked the patent in March 2004. The corresponding US patent US5500345 was yet granted 1996 with similar claims.

Criticism

It is extremely arguable whether this strict position is justified. Due to the more or less chaotic and unpredictable interplay between the amino acid residues in a peptide chain, the mere replacement of only a single amino acid residue can dramatically affect the affinity or specificity of an existing antibody.

The variable regions have about 120 amino acids, which makes 3.83×10^{41} potential variants.

Before this background, starting from a first-generation antibody with a given sequence, what expectation of success would a skilled person have to end up at the specific sequence of a given second- or higher-generation antibody?

The "antibody sonderweg" is also contrary to EPO's existing examination policy in other technical disciplines:

In Technical Board's decision T92/92, which related to a glide shoe, the board found that

> no ground can be seen why a novel, alternative solution to a known problem should be excluded from patentability for lack of inventive step for the reason that the problem has already been solved in a different manner.

In Technical Board's decision T467/94, which related to a pharmacological pyridinium composition, the board stipulated that

> the technical problem […] can be seen in the provision of further useful anti-ulcer agents. […] The question […] is whether the cited documents would have suggested [...] solving the […] technical problem in the proposed way.

Further, according to the guidelines of examination, Part C, Chapter IV, 9.8.2, a "technical problem" does not imply that the technical solution is an improvement over the prior art. Problem can be simply to seek an alternative to a known device or process. EPO's granting practice with respect to structural antibody claims is thus in conflict with established case law in other technical disciplines.

While target claim patents, toward which the EPO exercises a liberal examination policy, will oftentimes be used by target discovery companies and

universities, structural claim patents come into play once a specific mAb is developed for therapeutic use and are thus primarily used by pharmaceutical companies. While target discovery as such is definitely a costly matter, and deserves adequate patent protection, the development and approval of a new therapeutical mAb outranks the latter by orders of magnitude (DiMasi and Grabowski 2007). EPO's concept to (1) routinely grant functional claims on a theoretical antibody in case the target is novel, but to set (2) high bars with respect to structural claims on a second- or higher-generation antibody therefore seems to overcompensate target discovery companies and undercompensate pharmaceutical companies.

The fact that this policy is a mere logical continuation of EPO's policy when the first monoclonal antibody patents were filed, in which case patent claims related to mAbs that replace prior art polyclonal antibodies were rejected denied unless the former had surprising effects (see, e.g., Technical Board's decisions T36/90 and T499/88) provides cold comfort only.

Implications for the Therapeutic Antibody Industry

Structural antibody patents must be filed at a very early stage to avoid novelty problems. Oftentimes, one or more structurally defined lead candidates exist, but little is known about them beyond their sequence. Accordingly, functional characteristics of these lead candidates can only be determined at a later stage, i.e., through CROs.

If the EPO applies the above-described policy too rigidly, the successful patent prosecution of structural antibody patents may be put at risk. The development of new antibody therapeutics may thus become commercially unattractive at least in cases where the target is already known (i.e., second-generation antibodies), because, in the pharmaceutical industry, a patent is indispensable to protect R&D expenses. Otherwise, a newly approved antibody would soon become subject of generic competition.

However, the oft-cited "surprising effect" does not always have to be affinity. Other effects setting the subject antibody apart from prior art can also be used. Consider, e.g., clotting behavior, effector function, the target epitope to which the subject antibody binds, immunogenity, serum half-life, or stability.

Further, even if an applicant has no data with respect to these features at hand at the priority date, such data supporting a surprising effect can be submitted later on, even during prosecution, in case such data relate to features mentioned as such in the specification. For this reason, applicants should at least write a clause mentioning these features in a general fashion into the specification, to be able to react flexibly during prosecution.[13]

[13] Possible in the US and before the EPO, not possible in Japan and China.

3.2.4 The Policy of the USPTO

As regards target claim patents, the CAFC held in *Noelle vs. Lederman*[14] that the applicant did not provide sufficient support for claims to a human CD40CR antibody, because he failed to disclose the structural elements of human CD40CR antibody or antigen and was thus denied an earlier filing date. In fact, the earlier filing date related to an application which disclosed the mouse antigen mly, plus the ATCC number of the hybridoma cell secreting the mouse CD40CR antibody. However, quite remarkably, the court stated that

> Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen.

This decision has been confirmed in *Centocor vs. Abbott*,[15] in which the court argued as follows:

> While our precedent suggests that written description for certain antibody claims can be satisfied by disclosing a well-characterized antigen, that reasoning applies to disclosure […] where creation of the claimed antibodies is routine

The US position with respect to target claim patents is thus pretty much the same as that of the EPO. Accordingly, HGS's US-Patent 6,403,770, which corresponds to EP0939804 (that has eventually been allowed in Technical Board's decision T0018/09 and is discussed above), made this clear. The patent has been granted with the following main claim:

> 1. An isolated antibody or portion thereof that specifically binds to a protein consisting of an amino acid sequence of amino acid residues 1 to 285 of SEQ ID NO: 2.

The patent is still in force and has been and recommended for PTE by the DOH.

With respect to structural mAb claims, US case law seems not to require a "surprising effect" to accept non-obviousness. In the CAFC case *re Deuel*,[16] the court argued that

> the existence of a general method of isolating cDNA or DNA molecules is essentially irrelevant to the question whether the specific molecules themselves would have been obvious, in the absence of other prior art that suggests the claimed DNAs.

The USPTO Manual of Patent Examining Procedure ("MPEP") puts it similarly (see Section 2144.09)

> The existence of a general method of gene cloning in the prior art is not sufficient, without more, to render obvious a particular cDNA molecule

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[14] 355 F.3d 1343 (Fed. Cir. 2004).

[15] 2010-1144 CAFC.

[16] 51 F.3d 1552 (Fed. Cir. 1995).

Before this background, the often-made allegation that the EPO is more inclined than the USPTO to grant target claim patents is probably unjustified. However, as regards structural claim patents, the USPTO granting practice is in fact more liberal, as no surprising effect is required to establish non-obviousness/inventive step.

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Law Enforcement of Biotech Patents

Martin Quodbach

Abstract A contribution to the litigation of patents in Europe with special references to biotechnological inventions and to the practice according to the German system of patent enforcement.

Keywords IP · Patents · Infringement · Enforcement · Biotech · Injunction · Life sciences

1 Introduction

The prosecution of patents in Europe has achieved a rather high level of international harmonization. In spite of the duality of national patents and European Patent Convention (EPC)-based patents ("European Patents"), the substantive patent law has adapted commonly accepted standards relating to the patentability of inventions. On the other hand, the litigation of European Patents leads back to the provisions of national patent law, as European Patents effectively divide in independent national parts (bundle of patents), and thus independent patents.

This diversity makes it necessary to **deal with separate national legal consequences and effects of infringing a European Patent**. Art. 64 EPC stipulates that a European Patent confers on its proprietors from the date in which the mention of its grant is published in the European Patent Bulletin, in each Contracting State in respect of which it is granted, the same rights as would be conferred by a national patent granted in that State. Therefore, patent litigation—as any other national litigation—requires the knowledge of national statutory and case law regarding civil procedure. This includes general standards and—as the

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U. Storz et al., *Biopatent Law: European vs. US Patent Law*, SpringerBriefs in Biotech Patents, DOI: 10.1007/978-3-642-41293-6_2,

case may be—specific standards that have developed in IP and particularly in patent infringement cases.

Certain standards are based on the Directive 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights (**IPR Enforcement Directive**). But on one hand, these measures only intend to guarantee a minimum protection level; therefore national provisions may contain further sanctions for infringements. On the other hand, the aims of the IPR Enforcement Directive are formulated in general terms, leaving room for interpretation and discussions, if the national law and its level of protection indeed meet the intention of the directive.

In addition to this duality of European Patents and national patents, the efforts to create a unitary patent in Europe ("**Community Patent**") has proceeded. The Court of Justice of the EU on March 8, 2011 had held that the 2009 draft agreement on the European and EU Patent Courts is not compatible with EU law. Then, the EU Council on June 27, 2011 agreed on a further approach, encompassing an enhanced cooperation and dealing with specified provisions with regard to translations.[1] In 2012, the EU member states achieved a breakthrough agreement. On 11 December 2012 the European Parliament approved the Regulation of the European Parliament and of the Council implementing enhanced co-operation in the area of the creation of unitary patent protection and the Council Regulation implementing enhanced co-operation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements. Further, the Agreement on a Unified Patent Court was published by the Council of the European Union on 11 January 2013. The Agreement was signed on 19 February 2013 by 24 EU member states. It still has to be ratified by the contracting member states. The Agreement sets up a single and specialized patent jurisdiction. Further, on 31 May 2013 the Preliminary set of provisions for the Rules of Procedure ("Rules") of the Unified Patent Court were published whereas several aspects still are in discussion. The Unified patent Court is expected to come into operation in the first half of 2015. History shows that the forming of a court system is strongly influenced by (1) national interests in maintaining or establishing patent facilities and (2) concerns that the competency of a new founded system will not be sufficient. Thus, it would not be surprising, if the discussion will have to be continued. In addition, it is still not clear if the system of the new Community Patent will have any impact on substantial patent law. An important question is if the European Court of Justice will have an indirect jurisdiction on substantial questions with regard to the scope and the litigation of a Community Patent.

Against this background, this contribution examines the existing regulations and the enforcement of patents within the national court systems. Since it focuses on biotechnology-related questions, it seemed to be advisable to also give a short overview of the legal background of each case dealt with.

[1] See the press release on the EPO homepage. http://www.epo.org/law-practice/legislative-initiatives/eu-patent.html.

About 50 % of all patent lawsuits in Europe are filed in Germany (thereof ca. 50 % are brought before the Düsseldorf courts). Therefore, the German patent case law has a big influence on the patent protection in Europe. As far as a specific German practice of handling a case has been developed, the respective case law will be presented. The structure of this article thereby shall correspond to the development of a patent case from preparing an action until the final decision.

2 Identifying the Infringing Object, Documentation of Evidence Against the Background of the Burden of Proof of the Patent Owner

As the claimant has to prove the infringement of the patent, he has to present all facts that the court needs to evaluate the infringing article/process.

2.1 Preparing the Technical Facts of the Case (If the Claimant has Access to the Infringing Article)

In case of an invention related to mechanical issues, all relevant patent features may be observable at first sight. In contrast, chemical and biotechnical circumstances can often not be comprehended by a judge who has not been qualified in science. This is even true for courts with a high competency and experience in handling patent cases since each case touches different and individual fields of natural science.

Therefore, the preparation of a complaint needs to take into account that the court might not have gotten in contact with the technical background of the invention before. Further, the facts of the infringement have to be made clear in a manner that leads a judge step by step to the opinion that the patent indeed is infringed. With regard to biotechnical cases, this often requires to use expert opinions and analyses before filing a lawsuit.

The defendant will probably try to question not only the infringement itself but also the basis of the allegations brought forward by the plaintiff. Thus, not only the results of analyses made by the plaintiff will be relevant but also the way these analyses have been documented (regarding preconditions, documentation of intermediate steps, and the compliance with processing parameters). This aspect becomes relevant in particular, if the plaintiff does not outsource such preparatory work to (e.g.) an institute with high competence and a high reputation but takes recourse to internal resources (e.g., own personnel and laboratories).

Beside these objective requirements, the plaintiff also will have to anticipate the national laws of civil procedure relating to rules of evidence, in particular regarding the question which form of suitable evidence the court is allowed to

admit. According to German civil procedure law, the relevant surrounding circumstances can be confirmed by witness testimony of the persons involved in the corresponding preparations or by documentary evidence.

2.2 Gaining First Access to the Infringing Article

If the infringing article is not freely available or if the article itself cannot give evidence of the use of the patent (e.g., if the patent covers a manufacturing process), the patent owner (in the case of doubt) needs to apply for legal measures in order to get access to the facts necessary to file the patent infringement suit. Sometimes, the patentee can come up with indications for an infringement, but such information might not meet his burden of proof under the applicable national law.

Beside the established measures to ensure the national enforcement of intellectual property rights, the **IPR Enforcement Directive** deals with requirements to strengthen the patent owner in a pretrial stadium. Art. 6 Sect. 1 stipulates that the Member States shall ensure that, on application by a party which has presented reasonably available evidence sufficient to support its claims, and has, in substantiating those claims, specified evidence which lies in the control of the opposing party, the competent judicial authorities may order that such evidence be presented by the opposing party, subject to the protection of confidential information.

National statutory law had already provided for such measures to some extent before the IPR Enforcement Directive became effective. An often-cited example is the French "saisie contrefacon"[2] which was (and still is) frequently applied for by foreign companies in France in order to use the obtained information also in patent infringement suits in other countries. Also the English "Anton Piller (or now 'search') order"[3] based on case law is a well-known example of how to raise evidence by searching premises and seizing evidence without warning the infringer.

Before the IPR Enforcement Directive was implemented in Germany, the German courts had also already developed a practice enabling a patent holder to apply for judicial orders to enforce claims to inspect in-house circumstances in the infringer's premises. The German Federal Supreme Court decided twice on this subject matter[4]; the predominant problem was the degree of probability of infringement to be demonstrated by the claimant. The respective German case law required that the patent owner could show an adequate ("hinreichende") probability of infringement on basis of indications. Basically, this case law already

[2] Art. L. 615-5 French Intellectual Property Code.

[3] Anton Piller KG versus Manufacturing Process Limited Ch 55 in 1976.

[4] BGH GRUR 1985, 512—Druckbalken; GRUR 2002, 1046—Faxkarte.

fulfilled Art. 6 Sect. 1 of the IPR Enforcement Directive, which was then integrated as statutory law in the German Patent Act.[5]

For biotechnological cases, Art. 6 Sect. 1 of the IPR Enforcement Directive and the corresponding practices of national laws implicate several challenges resulting from technical difficulties. Biotechnology activities can hardly be experienced by just visually inspecting them, as it might be suitable in mechanical issues. The identity of a biological material can generally only be analyzed by complex tests. And even if a seizure of samples can be obtained by a provisional court measure, the patent owner (respectively, his representatives) need to orient themselves within the production process at the infringers premises to find out where to find the aim of the survey. And it will depend on the individual circumstances if such a sample actually has a stability that allows it to store it for later scientific analyses.

The main problem in preparing such judicial orders is therefore to anticipate the course of the intrusion of the infringer's premises and to prepare the disposition in order to collect evidence, while the legal framework as such treats biotechnical patent cases identically to other patent cases.

3 Determination of the Scope of Protection of a Patent Claim, Evaluation of Patent Features

The patent claims define the scope of protection conferred by the patent. In addition to the general rules of patent claim interpretation, biotechnological patent cases may raise special questions with regard to technical language, e.g., the description of products or methods.

3.1 General Rules of Patent Claim Interpretation

Art. 69 EPC stipulates that the patent claim is the source of the scope of protection, whereas the description and the drawings shall be used to interpret the claims. In addition, the Protocol on the Interpretation of Article 69 EPC says that Art. 69 EPC neither intends to limit the claim to the strict, literal meaning of the wording, nor to employ the description only in case of an ambiguity in the claims, nor intends to take the claims only as a guideline and to extend the protection to what—considering the description and drawings—the patent proprietor has contemplated. Art. 69 EPC rather has to be interpreted as defining a position between these extremes, combining a fair protection for the patent proprietor with a reasonable degree of legal certainty

[5] § 140c PatG.

for third parties. In this context, the patent also is characterized as its "own lexicon" when determining the meaning of the language of a patent claim.

Thus, the wording of a patent claim has to be read in a way a person skilled in the art understands the protection sought by the patent owner. Such a person has a technical background and thus the use of special technical terms may indicate the general meaning of such a term.

Decisions of courts in different EPC Member States with national parts of one European Patent actually should correspond with each other. Parallel foreign decisions may have an indicative effect, especially if they are issued by highly frequented courts (such as UK, French, or German courts). A recent German court decision postulated that German courts (at least) have to take in consideration foreign decisions which essentially deal with the same questions the German court has to answer.[6] But reality is somewhat different when cases are on balancing on the knife's edge.

For **biotechnological cases,** the wording of patent claims and technical terminology are of high relevance. This is a consequence of a widely used formulating and granting practice regarding biosequence claims (e.g., applying to primers, nucleic acid, DNA sequences).

Further, the Directive 98/44/EC on the legal protection of biotechnological inventions ("**Biopatent Directive**") contains instructions to determine the scope of protection for biotechnological inventions.[7]

Art. 8 Sect. 1 provides that the protection conferred by a patent on a biological material possessing specific characteristic as a result of the invention shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics.

Art. 8 Sect 2 stipulates that the protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to a biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through propagation or multiplication in an identical or divergent form an processing those same characteristics.

Art. 9 says that the protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material in which the product is incorporated and in which the genetic information is contained and performs its function.

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[6] German Federal Supreme Court, BGH GRUR 2010, 950—Walzenformgebungsmaschine.

[7] As also implemented in Sect. 9a German Patent Act.

3.2 Literal Scope of Protection of a Patent Claim and the Doctrine of Equivalents

Within the most patent systems, a patent infringement can be based either on a literal approach to the patent claim or a so-called *equivalent* infringement. The Protocol on the Interpretation of Article 69 EPC (Art. 2) requires that the protection includes elements which are equivalent to an element specified in the claims. The national case law in the different member states shows different approaches to the underlying problem. Some systems focus on the essentiality of a feature of a patent claim, others set their priorities on the same function and effect of the substituted feature and/or the obviousness of the substitution on basis of the patent description from the point of view of a person skilled in the art.

The questions to be dealt with often lead back to a basic balance between the economical and justified interest of the patent owner and legal certainty, which is also pointed out by the Protocol on the Interpretation of Article 69 EPC.

In particular, German courts have rendered a large number of decisions dealing with the doctrine of equivalents.[8] The legal practice requires that (1) the substitute feature objectively has the same effect as the corresponding substituted feature for the invention, that (2) a person skilled in the art is able to find the substitute feature and that (3) these efforts and considerations of the person skilled in the art are related to the patented invention, i.e., that he was able to conclude that the substitute features have the same effects taught by the invention. So the patent itself and the description are essential for any consideration that leads to the scope of protection beyond the literal meaning of a patent claim.

A recent decision by the German Federal Court of Justice could have a great impact on the doctrine of equivalence.[9] The court found that the substituted means were disclosed in the patent description as a further way to accomplish the effects of the invention. But the court held that the scope of protection of the patent claim is limited to substitute features, which have found an expression in the patent claim and that substitute features are beyond this scope if the description cannot be read as an explanation of the patent claim (but as an aliud).

This decision can also have an influence on future biotechnological cases, as biological systems can be highly error-tolerant. The above issue could be crucial for the question to which extent degeneracy of genetic codes and substitutions of separate parts of sequences can still be challenged under the principle of equivalence, if the patent claims do not explicitly cover deviations (e.g., by claiming identities expressed by percental correlations of biosequence listings). Also, the description could clarify the level of correlation which still meets the advantages

[8] Fundamentally: German Federal Supreme Court, BGHZ 150, 149—Schneidemesser I; GRUR 2002, 519 Schneidmesser II, GRUR 2002, 511—Kunststoffrohrteil, GRUR 2010, 523—Custodiol I, GRUR 2002, 527—Custodiol II.

[9] German Federal Supreme Court, BGH—Okklusionsvorrichtung, decision dated on May 10th 2001, file number: X ZR 16/09.

of the invention. But even without such explicitly named areas, equivalent infringements beyond the literal scope of protection—on the basis of German patent law—should generally remain possible.

3.3 Restrictions of Disclosed Industrial Applications of Biosequences

Art. 5 Sect. 3 Biopatent Directive stipulates that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application (see also the recital 22 of the directive). Recital 23 of the directive provides that a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention. So the naming of the industrial application remains essential in prosecuting patents. But these legal definitions do not clarify in which part of the application the industrial application has to be implemented.

According to the view of the German legislator, the industrial application has to be an essential part also of the *patent claim.*[10] The text of the Rule 29 Sect. 3 EPC corresponds to the wording of the directive; the European examination guidelines also refer to the disclosure in the patent *application.*[11] The relationship between national regulations and the EPO-practice has become subject of a discussion, also with regard to the question, if stipulations in national patent acts will restrict the national parts of a European Patent.[12]

Even if an industrial application has become part of a patent claim, it may still be discussed if the scope of the protection is in fact limited to the industrial application. The application could only be mentioned as an example or can be generalized. But if an industrial indication is named in the patent claim, this circumstance tends to result in a corresponding restriction of the scope of the patent.

On the other hand, also an absolute protection of a (chemical) compound can be restricted in order to balance the interests of the patentee and the defendant. So the Regional Court of Dusseldorf[13] ruled that a compound, although absolutely protected, was not relevant in a product, as the concentration was very low and did not have any functional meaning for the product (the industrial application of the patent related to a intermediate). The court considered it to be relevant that the use of the invention must be intended and expedient. So it still would be possible to overrule an absolute protection by common principles, for instance by balancing different interests.

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[10] See § 1a Sect. 4 German Patent Act.

[11] Part C Chapter VI, No. 5.4.

[12] Dolder, Fritz/Butler, Jeffrey M. (2008) Der Schutzbereich von Patenten/Scope of Protection of Patents, page 220, Köln.

[13] LG Düsseldorf, GRUR 1987, 896—Grasherbizid.

3.4 The Monsanto Versus Cefetra/Toepfer Case

Regarding the litigation of biotechnological patents in light of the Biopatent Directive, a decision of the European Court of Justice (EJC) dated on July 6, 2010,[14] has attracted Europe-wide attention. Monsanto Technology LLC enforced a patent claim focused on a gene conferring herbicide resistance on plants. The claims were directed to DNA as well as to plants transformed with a glyphosate resistance gene and methods of producing such genes. Monsanto alleged that its European Patent was infringed by the import of soy meal from Argentina to the Netherlands. In fact, the DNA within this meal was existent but obviously was not expressed to provide any herbicide resistance.

So the question was how the national provisions have to be interpreted against the background of Art. 9 of the Biopatent Directive which stipulates that the protection extends to all material in which the product is incorporated and in which the genetic information is contained *and performs its function*.

The ECJ ruled that the protection did not cover the soy meal because the DNA sequence encoding the glyphosate resistant gene could not perform its function in the dead soy meal material. Thus, the court ignored the wording of the patent claim by consulting general principles of the Biopatent Directive. The ECJ also used the opportunity to deal with the general relationship between the provisions of the Biopatent Directive regarding the scope of protection of a patent and the national rules implementing the guidelines. In this respect, the ECJ clarified that Art. 9 of the Biopatent Directive effects an exhaustive harmonization of the protection, so that national patent legislation is prevented from offering absolute protection to the patented product (the DNA) as such.

The possession of isolated DNA per se might not be patent relevant; but the ECJ has not defined whether the function of the DNA must be actual, continuous or could be activated under certain further circumstances. Also, critical voices are raised regarding the refusal of absolute protection of DNA sequence since the arguments of the ECJ are inconsistent with basic principles developed for other chemical compounds.[15]

But the restrictions on the absolute protection, according to the skeptical view by the ECJ, do not prevent the patent applicant to formulate further patent claims on basis of products attained by using the DNA sequence in several (e.g., initiating) process steps.

The decision of the ECJ has by all means a basic influence on the litigation of biotechnological patents under national rules of civil procedure. The decision makes clear that the Biopatent Directive sets a certain maximum standard of protection that cannot be exceeded by national patent legislation. This does not only affect the patent law itself but also the interpretation of the law by the competent courts.

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[14] Official Journal of the European Communities, 28.8.2010 C 234/7.

[15] See Hüttermann/Storz, Mitt 2011, 1; Krauß Mitt 2001, 54.

The national provisions have to be interpreted according to these standards. This means that, as far as the legal background and the subject matter of the Biopatent Directive (in particular the political and ethical background) influence future cases, the EJC has the sole authority to develop the future practice of defining the scope of protection of biotechnological patents. It will be the national courts′ duty to refer further questions to the ECJ as soon as a party raises controversial questions in this respect. That also could mean that the effectiveness of national patent systems will suffer, as a referral always means a significant delay of proceedings.

In light of the above, the ECJ in fact even has a greater influence on national patent jurisdiction as the EPC, as Art. 64 EPC respects national basics of conferring protection and interpreting patent claims (on the other hand, Rule 26 says that the Biopatent Directive shall be used as a supplementary means of interpretation). In any way, the future influence of the ECJ on national case law with regard to the scope of protection of a patent might also affect the national principles, for example, not only regarding the literal scope of protection of a patent but also the principle of equivalency.

4 Determination of Jurisdiction/ the Competent Court

Bringing a patent case to a court requires determining the national and local jurisdiction. The patentee should try to select a jurisdiction that is most beneficial for his needs. For the EPC Member States, the international jurisdiction is regulated in the Counsel Regulation (EC) No 44/2001 of December 2000 on jurisdiction and the recognition and enforcement of judgments in civil and enforcement matters ("Brussels I Convention").

As the general rule (and in case of doubt), a defendant can be sued in the country in which he is domiciled (Art. 2.2) or in which the defendant has got a branch, agency, or establishment (Art. 5.5). Pursuant to Art. 5.3, tort matters can be brought before the courts for the place where the harmful event occurred or may occur. Further, Art. 6.1 extends jurisdiction on several defendants if the claims are so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments from separate proceedings.

In patent cases, the jurisdiction based on the tort law and the territory where the infringement was located is highly relevant.[16] Efforts to concentrate the infringements of different national parts of a European Patent by different affiliated companies at one national court on basis of Art. 6.1 (co-plaintiffs, cross-border injunctions) are obstructed by different hurdles.

[16] ECJ Case C-68/93—Fiona Shevill, March 7th 1995, GRUR Int. 1998, 298.

The decision **Gat v LuK**[17] ruled that on basis of Art. 22.4 of the Brussels I Convention cross-border injunctions have to respect the exclusive competence of a national court to decide on the validity of a patent in an infringement case (as stipulated for example in France and in the UK). Such a scenario indeed does not make it attractive to pursue cross-border injunctions because of the delay of a lawsuit that will occur if the defendant raises a validity objection. And if a foreign national system does not even provide a separate proceeding to deal with the validity of the patent, the infringement lawsuit might even become inadmissible.

The decision **Roche v Primus**[18] ruled that multiple actions against foreign subsidiary companies regarding the infringement of different parts of a European Patent ("spider in the web" situation) in a single jurisdiction do not fall under Art. 6.1 of the Brussels I Convention. The legal findings in separate lawsuits could not be contradictory since national parts of a European Patent are governed only by national laws of that jurisdiction (Art. 64 EPC).

So the focus when dealing with cross-border infringements lies on the planning and coordination of multijurisdictional proceedings in different European Member States. Beyond that, the patentee can challenge the question of personal responsibility of other companies affiliated with the primary defendant. So a responsibility in particular can be based on complicity, for example if the business is a result from a division of labor. Also advertisement measures (e.g., of a parent company) can form a reason to establish a domestic infringement.

Finally, the competent court within a national jurisdiction has to be established. The EPC Member States have predominantly provided for a special jurisdiction for patent lawsuits. In Germany, 13 patent chambers at certain regional courts have been established while three of them are highly frequented (Dusseldorf being by far the most frequented).

5 Choosing the Adequate Litigation Procedure

5.1 Preliminary Injunctions Versus "Normal" Proceedings

The average duration of patent lawsuits in the European Member States varies. German-, Dutch-, and UK-based proceedings are well known as time-effective. A first instance decision can be expected in about one or two years (under favorable circumstances). But even such a period of time may cause unrecoverable damage to the patent holder. Against this background, several national court systems allow preliminary injunction procedures forcing the infringer to stop the infringement

[17] ECJ Case C-4/03, July 13th 2006, GRUR Int. 2006, 839.

[18] ECJ Case C-539/03; July 13th 2006, GRUR Int. 2006, 836.

immediately.[19] **German patent courts** have developed considerable case law providing for fast cease and desist orders.

The subject matter has first of all to be urgent in a sense that a further delay would be too detrimental for the claimant. Thereby, the urgency is denied if certain time limits have expired between the first knowledge of the infringement and the filing of the corresponding request (four weeks as a general rule).

Further, the preconditions of preliminary injunctions have recently been enhanced with regard to the presumptive validity of the patent. The grant of the patent does not per se indicate the reliability of the validity. The Higher Regional Court of Dusseldorf held that circumstances need to be established indicating that the patent has been "hardened." For instance, this might be the case if the patent has already survived contradictory invalidation proceedings (e.g., opposition, nullity action).[20]

Finally, a fast cease and desist order by the court requires balancing the interests of the parties. It has to be taken into account that a preliminary injunction might at not be maintained in the end.

In this context, a decision of the Higher Regional Court of Dusseldorf ("**Olanzapin**[21]") in 2008 has attracted a great deal of attention and was subject to intense controversial discussions. The court confirmed a preliminary injunction although before this decision, the German Federal Patent Court had revoked the patent in the first instance. At the time of the injunction, the invalidation proceedings were still pending at the German Federal Supreme court.

The Higher Regional Court held that the first instance decision was "obviously deficient.".At the end, the German Federal Supreme Court confirmed this opinion.[22] However, the handling of the Olanzapin case by the Higher Regional Court should not be expected to substantially change the case law in general. Rather, the decision marks a kind of juridical curiosity and has shown disunion of legally and technically qualified judges in evaluating a special (chemical) background.

Biotechnological cases often raise a further problem when preliminary injunctions are requested. A fast injunction procedure is only appropriate if the case is clear and simple, so that the court can handle it by following a summary procedure. It is not appropriate if either the patent itself raises questions (e.g., regarding the scope of the protection of the patent claims) or the infringing article's performances are in dispute. Thus, in cases where a biotechnological case necessitates the support of an (independent) technical expert, there is a high risk that the request will be dismissed.

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[19] See also Art. 9.1 a of the IPR Enforcement Directive which requires interlocutory injunctions.

[20] Higher Regional Court of Dusseldorf, InstGE 12, 114—Harnkatheterset.

[21] Higher Regional Court of Dusseldorf, InstGE 9, 140—Olanzapin.

[22] German Federal Supreme Court, BGH GRUR 2009, 382.

5.2 Border Seizure

Besides initiating court measures, the patent holder can try to enforce his intellectual property rights by involving European or national customs authorities. A border seizure by European authorities is subject to the Regulation (EC) No. 1383/2003.[23] Under this regulation, measures will regularly only be taken in response to applications of the patent holder. Also, an intervention requires a **concrete suspicion of an infringement**.

A weak point regarding border seizure proceedings is that the authorities have to evaluate the **obviousness of the infringement**. They will not have the time to go into detail in cases with a complex technical background. With respect to biotechnological cases, the custom authorities may easily be overburdened, as the performances of the products will not be self-explanatory at first sight. Therefore, border seizure has not become highly relevant for biotechnical cases yet.

6 Procedural Problems Regarding Biotechnological Cases

6.1 Staying of Infringement Proceedings on Grounds of Opposition Proceedings/Nullity Actions Against the Patent

The effectiveness of proceedings aimed at a cease and desist order by the court also depends on the duration of the action. The duration again depends on the way the validity of the patent can be disputed by the defendant. In this respect, the national patent systems differ.

Most European countries allow objecting the nullity defense directly within the infringement action. In other countries (e.g., Germany and Austria), the validity can only be challenged in a separate action while the infringement action can be stayed. Some systems provide both approaches (in particular France, Italy, and the UK).

The **German two-fold system's** advantage is that the infringement court can decide in each individual case if the nullity objection actually should influence the progression of the infringement action. The court only will stay the proceedings if the nullity action raises arguments with a substantial chance of success and likelihood for the defendant's position. Also, the invalidation proceedings can be concentrated with one competent court whose panels include judges with a technical background.

Most German courts (in particular the courts of Dusseldorf) are reluctant to use the option to stay the proceedings (what might also be a reason why patent holders frequently use Düsseldorf as a forum).

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[23] For Germany see § 142 a German Patent Act.

The infringement case will be stayed if—in the opinion of the court—the infringement action requires a preceding (binding) decision on the validity of the patent. In Germany, a stay of the proceedings currently leads to a delay of three years (in average). Biotechnological cases do not differ from patents concerning other technical fields in this respect.

6.2 Dependency on Expert Opinions

An infringement action (as well as a nullity action) will be delayed if a court has to obtain a written expert opinion. This can in particular affect biotechnological cases. Extensive chemical and biological knowledge cannot be presumed if an infringement court panel only includes judges with a legal education/training. It is generally time-consuming to determine an adequate expert, to wait for the written opinion and to hear the parties' opinion after the opinion is handed to the court and the parties.

In addition, German practice may evoke special legal questions when dealing with expert opinions. The expert opinion's duty is to give evidence to the court on certain facts. It is not the expert's duty to evaluate the scope of protection of a patent claim since this implies a legal evaluation. Further, the court may not just copy the statement of an expert without any own reflection.[24]

6.3 "Italian Torpedo"

Once a company is confronted with a patent infringement, this company itself can initiate another lawsuit based on a **negative declaratory action** aimed at a declaration that it does not infringe the patent. Art. 27.1 of the Brussels I Convention stipulates that where proceedings involving the same cause of action and between the same parties are brought in the courts of different Member States, any court other than the court first seized shall of its own motion stay its proceedings until such time as the jurisdiction of the court first seized is established.[25] This provision led to actions intending to delay patent cases by filing such negative declaratory actions.

In the past, several European Member States have become known for slow proceedings, such as Belgium and certain regions in Italy. Although knowing that the courts would not have jurisdiction on a case, such a "torpedo" helps the infringer to prevent the patent holder from bringing the case before the competent

[24] German Federal Supreme Court, BGH GRUR 2008, 779—Mehrgangnabe.

[25] Confirmed with regard to a "torpedo" by the ECJ December 9th 2003, Erich Gasser GmbH v MISAT Srl (Case C-116/02).

court. The case then can be brought forward only after the foreign court has decided on its jurisdiction.

Although this could be seen as an abuse of rights, this practice is still an issue of concern.[26] On the other hand, the ECJ decision Erich Gasser GmbH v MISAT does not explicitly exclude a misuse argument in such cases. There may still be room for exceptions in cases of an obvious lack of jurisdiction of a court. This discussion needs to be continued.

7 Legal Consequences of Infringing Biotechnological Patents

7.1 Standards Set by the IPR Enforcement Directive

The general provisions of the IPR Enforcement Directive postulate to establish measures, procedures, and remedies necessary to ensure the enforcement of intellectual property rights (Art. 1.1). Beside this general approach, the directive also names concrete aspects enabling the intellectual property holder to pursue his rights. These aspects include, in particular

- the right of information about the origin and distribution networks of the infringing goods, comprising details of the chain of supply and certain other persons involved (Art. 8),
- the right of information on the quantities of the infringing goods or services produced, manufactured, delivered, received or ordered, as well as the price obtained for the goods or services in question (Art. 8.2 b), **disclosure of acounts,**
- the recall and definitive removal or destruction of infringing products from the channels of commerce (Art.10.1),
- (in principle) an injunction aimed at prohibiting the continuation of the infringement including penalty payments in case of non-compliance with an injunction (Art. 11, 12), **cease and desist oder,**
- paying the right holder's damages in case of a willful or negligent infringement (Art. 13),
- (in principle) bearing the legal costs of the successful party (Art. 14) and
- publication of judicial decisions (Art. 15).

The directive has insofar met the elementary needs of the protection of intellectual property. In fact, most national laws in Europe had already complied with the basic legal consequences of infringing patents before. With respect to German

[26] See also Higher Regional Court of Dusseldorf, GRUR-RR 2009, 401 and 402, challenging the question if the "torpedo" really covers the same cause of action.

statutory, only a few additional rights of the patent owner had to be implemented, especially with respect to third persons involved in the infringement. The substantial interests of a patent holder had already been ensured by the German Patent Act and the respective case law before.

7.2 Damages and National Case Law on Tort

Art. 13 of the IPR Enforcement Directive substantiates how the national authorities shall provide for the damages. Negative economic consequences of the infringement, such as lost profits and unfair profits made by the infringer, shall be taken into account (Art. 13.1a). Art. 13.1b sets a minimum standard in this respect. The patentee can claim the amount of royalties or fees which would have been due if the infringer had requested authorization to use the intellectual property right.

Indeed, one focus of a patent case (after enforcing the disclosure of accounts) lies in the discussion if a patent owner can claim for the profits made by the infringer on behalf of the infringing goods/services. This aspect becomes relevant particularly in biotechnical cases. Patented biotechnical inventions often result from extensive and cost-intensive research and development efforts, especially in cases of a medical application. Thus, the purchase price of the developed products has to compensate the patent owner for the earlier expenses. This means that the margin of the product might be high since the pure production costs are rather low. Thus, the infringer would participate in the patentee's earlier endeavors.

In light of the above, German case law had to deal with the question to which extent the claimant can claim the infringer's profit. One of the questions is, which costs are deductible from the infringer's margin (only such cost that can be attributed directly to the infringing article—no general expenses[27]). Another question is, to which extend the patent itself was indeed causal for the unfair profit.[28] The infringer can argue for example that the company's reputation, trademarks, or other features of the product also influenced the customer's decision to buy the infringing product. In this respect, the German District Courts have ruled on several cases. The outcomes of the participation of the patent owner deviates from case to case and lies between 15 and 60 % of the profit.[29]

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[27] Fundamental: German Federal Supreme Court, BGH GRUR 2001, 329—Gemeinkostenanteil; GRUR 2007, 431—Steckverbindergehäuse.

[28] German Federal Supreme Court, BGH GRUR 2006, 419—Noblesse (trademark issue).

[29] OLG Düsseldorf InstGE 5, 251—Lifter, InstGE 7, 194—Schwerlastregal; LG Düsseldorf InstGE 1, 276—Klemmring, InstGE 8, 257—Tintentankpatrone; LG München I InstGE 3, 48—Rasenwabe; LG Mannheim InstGE 6, 260—Abschirmdichtung; LG Frankfurt a.m. InstGE 6, 141—Borstenverrundung.

8 Conclusion

Biotechnological patent cases are influenced by problems resulting from specific technical questions. This concerns the discovery of facts and the way of presenting evidence to the court. The enforcement of a patent is complicated in each stadium of a trial if a court has to consider (external) technical expertise.

Further, the litigation of biotechnological patents has become an own field of law since the Biopatent Directive came into force. This has not only affected the requirements for the prosecution of patents but also the scope of protection. It can be noted that the European Court of Justice is now entitled to rule on material patent law regarding the enforcement of patents. This will lead to further questions concerning the influence of European harmonization on national court and patent litigation systems.

Particular Aspects of US Patent Law in Biotechnologies

Scott D. Marty, Derek E. Constantine and Matthew Parker

Abstract A patent is defined as an exclusive right or rights provided by a government to an inventor for a certain period of time in exchange for the public disclosure of an invention. Patent protection can be sought in many of the major countries throughout the world. This chapter addresses the processes and rules followed by the Patent Offices of the USA and Europe. Although efforts have recently been made to harmonize the US patent system with Europe and the rest of the world, this chapter focuses on similarities and differences in the processes of obtaining patent protection in these two countries prior to the recent adoption of the most significant overhaul of the US patent system in more than half a century, the Leahy-Smith America Invents Act (AIA).

Keywords Priority · Conception · Reduction to practice · Novelty · Grace period · Written description · Information Disclosure Statement · Obviousness · Inventive step · Best mode · Enablement · Industrial application

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1 Priority

1.1 United States

Which patent application has priority in the United States focuses on the idea of "First to Invent". The US Patent and Trademark Office (USPTO) will consider the inventor who invents first—not the inventor who files an application with the USPTO first—to be the inventor of a particular invention. Invention in the USA consists of conception and reduction to practice.[1] Generally, an inventor is someone who "contribute[s] to the conception of the invention"[2]. An inventor does not need to be personally involved in reduction to practice. Conception is "the complete performance of the mental part of the inventive act"[3]. It is the moment in time when "a definite and permanent idea of the complete and operative invention" is formed in the mind of the inventor.[4] Conception of an idea is not enough to solidify an earlier invention date, though. There must also be reduction to practice.

Reduction to practice occurs when an invention stops merely being a concept and can actually be implemented. Actual reduction to practice occurs when a "claimed invention work[s] for its intended purpose"[5]. An invention does not need to be in its final, commercial state to be considered "reduced to practice", but it must be able to perform its basic purpose. Usually, though, an inventor never needs to prove her actual date of reduction to practice. The USPTO considers an invention to be *constructively* reduced to practice when an application claiming that invention is filed with the USPTO. The constructive date of reduction to practice will be the date of the application's filing, and an inventor will have to prove an earlier date of reduction to practice if she wants to overcome this presumption.[6]

An inventor will also need to show that she has used "reasonable diligence" in reducing her conceived invention to practice.[7] Courts do not require inventors to "drop all other work and concentrate on the particular invention involved" to show reasonable diligence, but an inventor must still account for the entire period with either affirmative actions on behalf of the inventor or acceptable excuses.[8] Any activity that is relied on by an inventor to show reasonable diligence must be

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[1] MPEP § 2138 (8th ed. Rev. August 9, 2012).

[2] Board of Educ. ex rel. Bd. of Trustees of Florida State University v. American Bioscience, Inc., 333 F.3d 1330, 1338 (Fed. Cir. 2003).

[3] Townsend v. Smith, 36 F.2d 292, 295 (Ct. Cust. App. 1929).

[4] *Townsend*, 36 F.2d at 295.

[5] Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986).

[6] *Hybritech*, 802 F.2d at 1376.

[7] MPEP § 2138 (8th ed. Rev. August 9, 2012).

[8] Emery, Howe, and Marcella v. Ronden and Rabel, 188 U.S.P.Q. 264, 269 (P.T.O. Bd. Pat. Int. 1974).

"directly related" to the reduction to practice of an invention.[9] Additionally, it is not enough to show reasonable diligence on behalf of just the inventor. An attorney must use reasonable diligence in preparing and filing the actual patent application.[10]

If the priority date of an invention is challenged by a second inventor, an inventor often does not need to provide evidence of reasonable diligence from the moment of conception to the moment of reduction to practice. An inventor only needs to show an earlier date of conception than the date of the second inventor and reasonable diligence from a *moment in time* before the second inventor's priority date. The entire period between a moment in time before the second inventor's priority date and the first inventor's reduction to practice needs to be accounted for, though.[11]

Finally, an inventor also must show that she did not abandon, conceal, or suppress an invention after her reduction to practice.[12] Courts will look at both *intentional* abandonment, concealment, or suppression and *inferential* abandonment, concealment, or suppression. Intentional acts require affirmative action on behalf of an inventor, such as stating in writing that an invention will be abandoned or delaying filing an application to prolong the secrecy of an invention.[13] Intentional acts require "more than the passage of time"[14]. In a situation with a prolonged delay between reduction to practice and filing an application with the USPTO, courts instead look to inferred abandonment, concealment, or suppression.[15] If a second inventor is able to show that a first inventor abandoned, suppressed, or concealed the first inventor's invention, the second inventor may be able to show that the first inventor is not entitled to her patent.[16]

If Inventor A conceives an invention, reduces it to practice, and ultimately files an application with the USPTO, his constructive invention date for priority purposes will be the application filing date. If Inventor B filed her application claiming the same invention as Inventor A before Inventor A's filing date, Inventor A will need to commence an interference with the USPTO[17] to show that he: (1) conceived the invention before Inventor B, (2) worked with reasonable diligence to reduce the invention to practice from a moment in time before Inventor B's conception, and (3) did not abandon, conceal, or suppress his invention after his reduction to practice. If Inventor A is able to show all of these points, he will be

[9] Naber v. Cricchi, 567 F.2d 382, 385 (Ct. Cust. App. 1977).

[10] MPEP § 2138 (8th ed. Rev. August 9, 2012).

[11] Griffith v. Kanamaru, 816 F.2d 624, 626 (Fed. Cir. 1987).

[12] MPEP § 2138 (8th ed. Rev. August 9, 2012).

[13] Fujikawa v. Wattanasin, 93 F.3d 1559, 1566–1567 (Fed. Cir. 1996).

[14] *Fujikawa*, 93 F.3d at 1567.

[15] Paulik v. Rizkalla, 760 F.2d 1270, 1273 (Fed. Cir. 1985).

[16] 35 U.S.C. § 102(g)(1) (2006).

[17] Interference procedures are complex processes that are beyond the scope of this explanation. *See* MPEP § 2138 (8th ed. Rev. August 9, 2012) for additional details.

successful in showing his actual date of invention—and earlier priority date for his invention. The USPTO will then consider Inventor A, and not Inventor B, to be the inventor for the invention in question—despite Inventor B's earlier filing date.

1.2 Europe

While the US system of "First to Invent" can lead to very complex results, the European (EP) system is far simpler. Instead of focusing on the inventive date, the EP system focuses on the filing date of an application or the filing date of an application from which priority is claimed. The EP system, therefore, is a "first-to-file" system. When considering which of two inventors should be awarded an earlier priority date (and thus a patent), all that matters is the filing dates of both applications. It does not matter if an inventor conceived of something first; the timing of an invention's conception and reduction to practice does not matter at all. An EP patent belongs "to the person whose [EP] patent application has the earliest date of filing, provided that this first application has been published"[18]. This first-to-file system is created in part by the requirement that the application eventually publishes.

Eventual publication matters during patent prosecution with the European Patent Office (EPO) because the first-to-file system is based on EP's strict novelty requirement. Article 54 explains that the state of the prior art at the time an application is filed will include the content of other EP applications filed prior to that date.[19] If an application—or eventual patent—is filed before a second application, the first applicant will get priority. If the first applicant withdraws the application from prosecution before it publishes, the second applicant will still be able to get a patent. If the first applicant withdraws the application after it has published, neither applicant will be able to get a patent since the first application prevents the second application from being novel.[20] Because of this first-to-file system, ensuring a filing represents a complete application is incredibly important in EPO prosecution. But, as long as an application is effective enough to get to the point of automatic publication at 18 months after filing, the application will be able to claim priority over anything filed after its filing date that cannot claim priority to some even early application.

1.3 The America Invents Act

The majority of countries use systems similar to EP's first-to-file system for determining priority. The America Invents Act (AIA)[21] is an attempt by the USA to

[18] European Patent Convention art. 60(2) (2010).

[19] European Patent Convention art. 54(3) (2010).

[20] Novelty will be further discussed *infra*.

[21] The very basics of the AIA will be discussed in this text, but the full details of the AIA are beyond the scope of this text.

harmonize its patent system with the patent systems of the majority of the world. The major change in the AIA, though, is the US's attempt to adopt a priority system similar in nature to the EP first-to-file system. Under the AIA, the USA will transition away from its first-to-invent system, no longer requiring applicants to show conception and reduction to practice after the AIA effective date of March 16, 2013. The USA will adopt a first-inventor-to-file system, thus focusing almost exclusively on an application's filing date. The current first-to-invent system will still be used for any applications filed up to the effective date, and those applications will continue to operate under the current first-to-invent system until their terms expire, which will be twenty years from their dates of filing. Additionally, any application that is a continuation of an application or patent filed before the effective date will also operate under the first-to-invent system. So, in addition to the first-inventor-to-file system that the AIA will create in the USA, patent professionals will still use the first-to-invent system for years to come.

2 Novelty

2.1 United States

For an invention to be patentable in the USA, all the elements or limitations of each claim to that invention must not be disclosed anywhere in a prior art reference. Simply put, the invention must be new. Novelty in the USA is examined on the basis of single prior art references. If all the elements of a single claim are disclosed in a single prior art reference, then the claim lacks novelty because the information already exists in the public knowledge—the claim is anticipated by the prior art reference.[22]

While each claim to an invention must be novel—not disclosed in any prior art reference, there are a variety of specific rules and exceptions that operate under US novelty considerations. First, there must not be use of the invention by other parties or public knowledge of that invention in the USA before the applicant's date of invention.[23] If other parties are using the invention or there is public knowledge of the invention before the applicant "invented" her invention, then the applicant's invention is not novel and does not deserve patent protection. But,

[22] If a claim is anticipated by multiple references—without any one reference disclosing all of the claim elements—the claim may be *obvious* in light of the prior art references. Obviousness is discussed *infra*.

[23] The USPTO will examine the application on a claim by claim basis, breaking each claim into its separate elements. The USPTO will then attempt to find a prior art reference that contains each element of an individual claim. For simplicity's sake, though, this text will refer to the application as a whole rather than repeatedly stating "each element of each claim of an application" 35 U.S.C. § 102(a) (2006).

unlike other patent systems, the US system is only concerned with use or public knowledge in the USA. Published works are another story, though.

If an invention is publicly disclosed or described in a printed publication anywhere in the world before an applicant's date of invention, then the applicant's invention lacks novelty.[24] The USA broadens its scope here by considering the entire world, and the USPTO and US courts have taken a very broad view of what is considered "public". Published work must be cataloged by the titles or categories of articles to be considered public, but otherwise there are very few limitations.[25] A simple way to view this requirement is that, if a document has been published in any language in any country, it probably can serve as prior art and destroy novelty of a later invention—assuming of course that it discloses the invention in question.

Additionally, an applicant's invention will lack novelty if it is disclosed in a US patent application or an international, Patent Cooperation Treaty (PCT) application[26] filed by another party before the first applicant's date of invention.[27] The second application must eventually publish in English for it to be considered prior art. But the USPTO will not consider the second application's prior art date to be its publication date. The prior art date that the first applicant must beat is the second applicant's filing date. With a public disclosure or a printed publication as discussed above, the USPTO will focus on the publication date of that document. An inventor simply must show that she invented before a printed publication was published that disclosed her invention. But with certain US and PCT applications, the date of filing of the second application is what matters for novelty purposes—not the date of publication. Even if an inventor can show a date of invention that is prior to the publication of the problematic US or PCT application, the inventor's invention may still lack novelty—and thus be unpatentable—if the US or PCT application was filed before the inventor's date of invention. So at the time of filing, an applicant may not know of any other applications or patents that disclose her invention. But if an application later publishes or issues as a patent that discloses her invention and was filed before her date of invention, she will not be able to receive a patent on her invention due to a lack of novelty.

Finally, an applicant's invention may lack novelty if the invention was created by another in the US prior to the applicant's invention.[28] While this is an important consideration, this issue is really at the heart of the US's first-to-file system, discussed above. Briefly, an inventor must have conceived of an invention first. If someone else conceived of the same invention first, the second invention lacks novelty, and the second inventor will not be able to receive a patent on her

[24] 35 U.S.C. § 102(a) (2006).

[25] There are famous examples of the "lost" document that was published in a foreign language in a foreign country that has served as prior art.

[26] The PCT application must designate the USA and eventually be published in English.

[27] 35 U.S.C. § 102(e) (2006).

[28] 35 U.S.C. § 102(g)(2) (2006).

invention—even if she was completely unaware of the prior invention and independently created the invention herself.[29]

It is important to realize that the activities destroying novelty discussed above all require actions by *parties other than the inventor*. The inventor's own activities can also destroy novelty, but there are certain grace periods for actions that can include the inventor's own activities discussed below.

2.1.1 Grace Periods in the USA

In the USA, the applicant has a set one-year grace period to submit an application that is triggered by a variety of situations, some of which are similar to those already discussed. If an invention is patented or described in a printed publication anywhere in the world or if an invention is in public use or on sale in the USA, the applicant has one year from that date to file an application before she will be barred from patenting.[30] There are two important differences between these grace periods and the novelty information already discussed. First, the actions can be done by anyone, including the inventor. For example, if an inventor presents and publicly uses her invention at a conference before she has filed an application, she will then have one year from that date to file her application before she will no longer be allowed to patent her invention. An *inventor's own activity* can prevent her from being able to patent her invention. But the grace periods are meant to give the inventor some protection regarding her activity, as well. She can disclose her invention, sell it, and take other actions *as long as* she files an application for the invention within one year. Second, the date in question is not the date of invention as in the novelty issues discussed above. Instead, the USPTO will consider whether something occurred more than one year before an application was filed. So, the date being examined will be the date of filing.

An inventor who files applications in other parts of the world will need to ensure that no foreign application issues as a patent one year before she files an application in the USA. Also, the "public use" and "on sale" bars apply only if they occur within the USA. As discussed in the novelty section above, the USPTO draws distinctions between certain events happening in the USA or in a foreign country. The invention can be in public use or on sale in a foreign country more than one year before filing without triggering this particular bar. Additionally, the "on sale" bar applies to actual sales or offers to sell; but it only applies to actual sales of or offers to sell the invention itself—the underlying object being patented. It does not apply to actual sales of or offers to sell the rights or licenses to the invention. An applicant can offer to sell or actually sell her intellectual property

[29] Under US copyright law, two separate authors can have a copyright to the same work if both authors completely independently created the work—not realizing that a duplicate work was created elsewhere. That concept is not allowed in US patent law.

[30] 35 U.S.C. § 102(b) (2006).

rights to the invention without triggering this particular bar. She simply cannot offer to sell or actually sell the underlying, inventive object.

2.2 Europe

The EP's approach to novelty is simpler than the US's approach, but it is also stricter. The meaning of novelty in the EP system is essentially the exact same as in the USA; for any invention to get a patent, it must be new. An invention is considered new if it does not form part of the prior art, referred to as the "state of the art"[31]. The EP's approach looks at the state of the art at the time an application is filed. The state of the art is far more inclusive than the US's prior art. The state of the art includes "everything made available to the public by means of a written or oral description [in any language], by use, or in any other way" before the application was filed.[32] While the USA makes distinctions between certain activities happening in the USA compared to other countries, there is no concern over activities happening just in the EP. Even if information is disclosed to a single individual of the public, the disclosure can be enough to destroy novelty if the person is legally free to further disclose that information.

The USA and EP take similar approaches to patent applications comprising part of the prior art for novelty considerations, though. The EPO considers the state of the art to include EP patent applications as of the dates of their filing, not the dates of their publications, as long as the applications eventually publish.[33] This standard goes to the heart of the EP first-to-file system discussed above, as the US standard goes to the heart of the first-to-invent system mentioned previously. An applicant can run into a similar situation as in the USA where an applicant may be completely unaware of any publication disclosing her invention at the time she files her application. But if a second application later publishes disclosing her same invention and has an earlier filing date, her invention will lack novelty because the second application was technically considered to be part of the state of the art at the time it was filed. Of course, the EP's approach looks only to the dates of filing and not the dates of invention.

This strict novelty can cause problems to some US applicants because they are used to the grace periods allowed in the USA. Any US applicant wishing to eventually receive an EP patent must be sure not to disclose her invention before filing a patent application from which a subsequently filed EP application can claim priority.

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[31] European Patent Convention art. 54(1) (2010).

[32] European Patent Convention art. 54(2) (2010).

[33] European Patent Convention art. 54(3) (2010).

2.2.1 Grace Periods in Europe

There are no equivalent grace periods of the US's system in the EP. This hard limit comes back to the EP's requirement of complete novelty in any application.[34] If there was any patent or printed publication describing the invention anywhere in the world prior to filing an application in the EP, there will be a lack of novelty, and thus, no patent is possible. Public use prior to filing will also serve as a complete bar in the EP. Interestingly, though, an offer to sell or an actual sale will not necessarily bar novelty as long as there is no public disclosure of the details of the invention—meaning no one has a chance to inspect the invention itself. The concern in the EPO comes back to complete novelty. As long as an applicant does not disclose information about how an invention works or allow anyone to determine how an invention works by inspecting the item itself, novelty should be maintained. But an applicant's own activity also can serve as an instantaneous bar if an applicant discloses information about her invention to the public.

There are two minor grace periods that the EPO allows, though they are very limited in scope and are not similar to those offered in the USA. First, the EPO grants a six-month grace period for an inventor to file an application if there was an "evident abuse" in a disclosure against the hopeful applicant.[35] This type of disclosure will most commonly occur if a party violates a confidentiality agreement with the applicant and illegally discloses her invention to the public. In that situation, the EPO recognizes that, through no fault of the applicant's, her intellectual property rights have been violated. So, the EPO will grant the applicant six months to file her application even though the invention has technically been made part of the state of the art. Second, the EPO grants another six-month grace period for applicants that have displayed their inventions at official exhibitions that fall within strict terms set out in the Convention on International Exhibitions.[36] Applicants do not often use this particular grace period, so it will be important for applicants to review the exact terms of the grace period if they ever wish to rely on it.

2.3 The America Invents Act

The AIA will affect novelty in the USA since the old first-to-invent system will be replaced with the new first-inventor-to-file system. Similar to the EP system currently, the first-inventor-to-file system in the USA will only be concerned with the filing date instead of looking at both the filing date and the date of invention depending on the situation. The full impact on novelty will not be understood for a

[34] European Patent Convention art. 54(2) (2010).

[35] European Patent Convention art. 55(1)(a) (2010).

[36] European Patent Convention art. 55(1)(b) (2010).

while, but the new novelty focus on filing date was be implemented with the remaining AIA changes on the effective date of March 16, 2013.

3 Written Description

3.1 United States

An applicant's specification must meet three distinct requirements in the USA: written description, enablement, and best mode.[37] The first requirement, written description, requires applicants to submit a full description of the claimed invention that a person having ordinary skill in the particular art would understand at the time of filing, setting an objective standard to judge the written disclosure. The written description serves both to explain what is encompassed in the invention and to show constructive possession of the claimed invention. Since the USPTO will treat the filing date as the constructive date of invention as discussed above, the written description serves to show in sufficient detail that the inventor had the actual invention. Without a clear written description, the USPTO would not be able to assume the applicant had invented the claimed invention as of the date of filing.

More commonly, though, the written description serves to limit the scope of any claims in a first application or in any future amendments to those claims or applications that seek priority from the first application. First, claims in an application must conform to the written description of that application. The applicant cannot provide a written description with extremely general details and then argue that any claim that could be written within the extremely broad language can be supported by the written description.[38] The application also cannot describe one invention in the written and then claim another in the claims.[39] Again, the written description needs to support the claims, and alternatively, the claims need to be supported by the written description.

Any amendments to the claims in an application or any later applications that want priority from that first application also must be able to find support for the amendments or new claims in the written description of the first application filed. The USPTO is particularly concerned with the claims of an existing application being broadened to include information that was not in the written description or an application that was just filed claiming priority from a previously filed application that does not contain the same subject matter in the earlier written description. Both situations would allow applicants to get earlier filing dates on "inventions" that they may not have actually invented until later.

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[37] 35 U.S.C. § 112 (2006).

[38] Fujikawa v. Wattanasin, 93 F.3d 1559 (Fed. Cir. 1996).

[39] Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998).

While US courts do enforce the written description requirement, they are generally open to an applicant pointing to a variety of areas in any specification to show written description support for any future amendments or later applications. US courts are even willing not to require writing in showing written description support. Courts have found written description support in drawings alone.[40] Information does not necessarily have to be in order or described the same way. Courts have not been open to enveloping the written description requirement into enablement, but they are willing to take a very broad approach to the requirement and allow applicants to pick and choose what portions of a written description provide support for later changes.[41]

3.2 Europe

The EP courts do not make a strong distinction between written description and enablement. Typically, the EP courts will consider a disclosure to be sufficient if the full scope of a claim is adequately enabled by disclosing methods of practicing the invention in the specification.[42] But the EPO does require an application to "disclose the invention in a manner sufficiently clear and complete" for it to be practiced by someone skilled in the art at the time of filing[43]. Additionally, an application's claims must "be supported by the description."[44] So even though the EP courts do not make a noticeable distinction between the written description and enablement, it would be a mistake to assume that there is not a written description aspect of an application in the EP system.

The EP system tends to be much stricter than the USA in requiring support from a written description in any additional amendments or future applications seeking priority from an early application, though. The EPO requires that any amendments to a current application be supported clearly and unambiguously on the description in the application that was originally filed; any amendments that extend the application subject matter "beyond the content of the application as filed" are strictly forbidden.[45] This standard is so strict that it typically requires word-for-word support from the application. The applicant must be able to point to the exact information in the exact order in an application for the EPO to consider there to be disclosure support. A similar requirement applies to any later applications that seek to claim priority to an early application. The EPO will not allow any later

[40] Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555 (Fed. Cir. 1991).

[41] Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co., 598 F.3d 1336 (Fed. Cir. 2010).

[42] Martina Schuster, *Sufficient Disclosure in Europe*: *Is There a Separate Written Description Doctrine Under the European Patent Convention*? 76 UMKC L. Rev. 491 (2007).

[43] European Patent Convention art. 83 (2010).

[44] European Patent Convention art. 84 (2010).

[45] European Patent Convention art. 123(2) (2010).

application to claim the earlier filing date of a previous application unless the applicant can point to direct and unambiguous support in the early application for each claim in the later application; the previous application must "specifically disclose" any elements in the later application.[46] Again, the safest assumption for an applicant will be to assume that word-for-word support will be required. The "pick and choose" approach taken by the USA—allowing great flexibility in finding written disclosure support in an application—will not work in the EP system.

These strict requirements are dangerous to an applicant that cannot point to word-for-word support because, in the EP system, simply getting the examiner to agree with an amendment or priority is not all that matters. Any matter that is added after the date of filing may serve as a ground for revoking a patent. The EPO applies such a strict standard that an applicant-turned patentee can find herself without a patent if information was added and the patent is ever challenged. The strict requirements regarding written disclosure in applications go back to the EP's first-to-file system. The entire EP patent system revolves around who filed first, not who invented first. So, the ability to get priority to an earlier filing date for a later filed application can be a huge advantage for an inventor. In an attempt to protect inventors in general from applicants looking to gain unfairly by broadening claims or using an earlier filing date unjustly, the EPO demands strict adherence to this standard of literal—and usually word-for-word—disclosure support.

3.3 The America Invents Act

It will be interesting to see if the AIA's shift of the USA from a first-to-invent to a first-inventor-to-file system will also lead to a shift in US courts from applying a very loose and broad written description requirement to demanding a stricter standard. Since the EP applies a very strict standard based on its first-to-file system, US courts may begin to create similar standards in the USA after the AIA goes into effect. Only time will tell.

4 Information Disclosure Statements

4.1 United States

Applicants in the USA are required to file an Information Disclosure Statement (IDS) with the USPTO, in which applicants must disclose any relevant prior art that they know of—such as patents, other applications, or scientific journals—because the USPTO requires "a duty of candor and good faith in dealing with the [USPTO], which includes a duty to disclose to the [USPTO] all information known to that

[46] European Patent Convention art. 88(4) (2010).

individual to be material to patentability"[47]. Applicants must report any references that are material to the patentability of their applications, so examiners may determine whether the references will prevent a patent from issuing. References are "material" to the patentability of applications and thus need to be disclosed, if they are "not cumulative to information already of record or being made of record in the application" and they establish a prima facie case of unpatentability or they "refute[], or [are] inconsistent with, a position the applicant takes" concerning patentability.[48] Applicants also must look to "[p]rior art cited in search reports of a foreign patent office in a counterpart application" and "[t]he closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines" to identify any references that are material and should be disclosed to the USPTO.[49] Additionally, courts have determined that an applicant should be required to disclose any substantive prosecution documents of any applications that contain substantially similar claims to the applicant's current application.[50] Adding even more to this duty, courts have found that applicants may not rely on an examiner to remember her office action from one application to another. So if one examiner is working with one applicant on a variety of related applications, the applicant must disclose all of the examiner's activities between each of the applications back to the examiner.[51]

While the language provided by the US courts and the USPTO is very broad to encourage applicants to disclose references, applicants are disclosing more and more references to the USPTO to meet this disclosure requirement. Also, applicants are desperate to avoid any claims that they withheld any references known to them because they want to avoid any charges of inequitable conduct. Inequitable conduct is often called "the 'atomic bomb' of patent law" because of the horrible outcomes of any successful inequitable conduct claims against an applicant.[52] When courts find inequitable conduct for any claim in a patent, the *entire patent* then becomes unenforceable. Even worse, any finding of inequitable conduct in one patent in a family of patents may lead to other, related patents becoming unenforceable. With a broad duty to disclose and the chance of inequitable conduct charges if applicants fail to disclose anything, the number of references disclosed has become enormous. The growing number of references have caused significant problems for applicants and the USPTO given the time and expense of preparing, filing, and reviewing these references.

[47] 37 C.F.R. § 1.56 (2012).

[48] 37 C.F.R. § 1.56 (2012).

[49] 37 C.F.R. § 1.56 (2012).

[50] Dayco Products, Inc. v. Total Containment, Inc., 329 F.3d 1358 (Fed. Cir. 2003).

[51] McKesson Information Solutions, Inc. v. Bridge Medical, Inc., 487 F.3d 897 (Fed. Cir. 2007).

[52] Therasense, Inc. v. Becton, Dickinson and Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011).

The US courts have attempted to reduce the number of references filed by making a claim of inequitable conduct harder to prove. Generally, inequitable conduct requires intent on the part of an applicant—though courts have applied different "intent" standards—and the reference in question must be material to patentability. Recently, the US courts held that a successful inequitable conduct accusation required an applicant to have acted "with the specific intent to deceive" the USPTO to show the intent element—clarifying what intent was required. Additionally, the courts held that whether a reference is material now must be considered under a "but-for" standard rather than the variety of standards previously applied by the courts. Any reference that was not disclosed to the USPTO can only be considered material "if the [USPTO] would not have allowed a claim had it been aware of the undisclosed prior art".[53] The courts also stated that the intent and materiality requirements should be considered independently of one another—reinforcing that there are two requirements that must both be shown. Finally, an applicant also may show that she failed to disclose a reference for another reason besides attempting to deceive the USPTO. Generally, the US courts have tried to make an accusation of inequitable conduct much harder to prove. Since it will take a while for applicants to see exactly how courts will apply these new standards, the safest approach for applicants currently is still to disclose any references that may be found to be material. Given the confusion in the USA regarding IDSs and disclosure expectations in general, applicants tend to operate under a simple rule: when in doubt, disclose.

4.2 Europe

While many requirements from the EPO are tougher to meet than their US counterparts, in this situation the requirement is much easier to meet; there is no duty to disclose prior art references to the EPO that are known to the applicant. The closest that the EPO comes is providing that it may "invite the applicant to provide information on prior art taken into consideration".[54] While the applicant must respond to the request—in fact, the application is considered withdrawn from prosecution if the applicant does not respond—there does not seem to be any consequences if an applicant fails to disclose all of the references she considered.[55] Considering the dire consequences for applicants in the USA who fail to disclose even remotely material references, the EP's approach is significantly easier on the applicant.

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[53] *Therasense*, 649 F.3d at 1291–1292.

[54] European Patent Convention art. 124(1) (2010).

[55] European Patent Convention art. 124(2) (2010).

5 Obviousness

If patents were awarded for the most trivial of advances over the prior art, two undesirable outcomes would occur: (1) the number of patents would expand dramatically, and (2) those skilled in the art would potentially be hindered by the resulting patent thicket. In other words, individuals would be hindered from practicing inventions otherwise obvious to those skilled in the art. In both the USA and Europe, patent law provides safeguards against the patenting of these trivial advances. In the USA, this safeguard takes the form of the non-obviousness requirement. In Europe, this safeguard takes the form of the inventive step requirement.

5.1 United States: Non-Obviousness

In the USA, the test for non-obviousness protects against the patenting of trivial advances and is codified in 35 U.S.C. §103.[56] The application of this statute has evolved over time, largely guided by two US Supreme Court cases: *KSR v. Teleflex*[57] and *Graham v. John Deere Co*., which deal with tests of non-obviousness and secondary considerations, respectively.[58]

5.1.1 35 U.S.C. §103

Whereas anticipation, per 35 U.S.C. §102, requires that a single prior art reference disclose each and every limitation of a claim,[59] non-obviousness allows the use of multiple prior art references. Specifically, where each and every limitation of a claimed invention is *not* described in a single prior art reference, a non-obviousness inquiry may be performed to determine whether the claimed invention is obvious based on one prior art reference in light of one or more other prior art references. The non-obviousness inquiry is described in 35 U.S.C. §103(a), which states in part that "[a] patent may not be obtained… if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains".[60]

Limited exceptions exist, however, where two or more references would otherwise form a basis for an obviousness rejection. If one or more references are

[56] 35 U.S.C. § 103 (2004).

[57] *KSR Int'l Co. v. Teleflex, Inc*., 550 U.S. 398 (2007).

[58] *Graham v. John Deere Co*., 383 U.S. 1 (1966).

[59] 35 U.S.C. § 102 (2004).

[60] 35 U.S.C. § 103(a) (2004).

cited as part of an obviousness rejection and qualify as prior art only under 35 U.S.C. 102(e), (f), or (g), then patentability is not precluded if "the subject matter [of the cited reference(s)] and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person".[61]

5.1.2 Teaching–Suggestion–Motivation Test

Patentable inventions often comprise two or more pieces of prior art. To protect against hindsight bias[62] and an erroneous finding of obviousness by examiners, the courts have used what is commonly referred to as the teaching–suggestion–motivation (TSM) test.[63] The TSM test requires, as the name implies, a teaching or suggestion within the prior art that would motivate a person having ordinary skill in the art to combine the prior art references to produce the claimed invention.[64]

The TSM test was used extensively by the courts, particularly the Federal Circuit, for several years. Recently, however, the applicability of the TSM test has been weakened in light of *KSR v. Teleflex*. In *KSR*, the Supreme Court pushed back against the fairly rigid TSM test and gave more credit to the ability and creativity of a person having ordinary skill in the art.[65] The Court stated that "[a] person of ordinary skill is also a person of ordinary creativity, not an automaton".[66] More particularly, the Court held that the application of "obvious to try" considerations should not be precluded when assessing non-obviousness.[67] Consequently, although the Court loosened the strict requirements of the TSM test, it did so at the risk of enhancing hindsight bias. Although the Court in *KSR* did not eliminate the TSM test, its application has been weakened to that of a "helpful insight".[68]

5.1.3 Secondary Considerations

In *KSR*, the Court also emphasized the role of so-called secondary considerations in any obviousness inquiry.[69] Secondary considerations are factors that provide

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[61] 35 U.S.C. § 103(c) (2004).

[62] Hindsight bias refers to the concept that many patentable inventions appear obvious with the benefit of hindsight, despite not being obvious to those skilled in the art prior to their disclosure.

[63] *See*, *e.g.*, *KSR Int'l Co.*, 550 U.S. at 407.

[64] *Id.*

[65] *Id.*

[66] *KSR Int'l Co.*, 550 U.S. at 421.

[67] *Id.*

[68] *Id.* at 418.

[69] *KSR Int'l Co.*, 550 U.S. at 406; secondary considerations are also known as *Graham* factors due to the case in which they were first cited. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966).

insight into the subject matter in question and include, but are not limited to, the interrelated teachings of multiple patents; demands known to the design community; knowledge possessed by a person having ordinary skill in the art and reasonable inferences employed thereby; the nature of the problem to be solved; the content of scientific literature; market demand; and the use of items beyond their primary purpose.[70] For example, in unpredictable fields, a person of ordinary skill in that art will be presumed by the courts to have less creativity than one in a more predictable field for the purposes of a non-obviousness inquiry.

The lower courts appear, to some extent, to be following the Supreme Court's *KSR* non-obviousness inquiry[71]; therefore, one should remain mindful of secondary considerations when dealing with the patentability requirement of non-obviousness in the USA.

5.2 Europe: Inventive Step

In Europe,[72] the patentability requirement of inventive step is the equivalent of the requirement of non-obviousness in the USA. Article 27 of the TRIPS Agreement supports this equivalence, indicating that the term "'inventive step'… may be deemed by a Member to be synonymous with… 'non-obvious'".[73] Inventive step's similarity to non-obviousness is further described in Article 56 of the European Patent Convention (EPC), which states that "[a]n 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".[74]

Although the two requirements may be similar, each is subject to distinct methods of analysis. To determine whether an invention is not obvious to a person skilled in the art, the problem and solution approach is applied by both the EPO and the European courts.

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[70] *See generally KSR Int'l Co.*, 550 U.S. at 418 (citing secondary considerations throughout the opinion).

[71] *See*, *e.g.*, *Perfect Web Techs.*, *Inc. v. InfoUSA*, *Inc.*, 587 F.3d 1324 (Fed. Cir. 2009).

[72] Unless otherwise indicated, Europe as used herein refers to the application of patent law by the European Patent Office (EPO).

[73] Trade-Related Aspects of Intellectual Property Rights art. 27, n5, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 I.L.M. 81 [hereinafter TRIPS].

[74] European Patent Convention art. 56, 14th ed. Available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar56.html.

5.2.1 Problem and Solution Approach

The problem and solution approach is a three-part inquiry.[75] First, the closest state of the art is identified. Second, this closest piece of prior art is used to determine the objective technical problem addressed by the invention. Third, one must consider "whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person".[76]

The closest state of the art must be identified first. According to the EPO Boards of Appeal, the closest state of the art "is generally that which corresponds to a similar use or purpose and relates to the same or a similar technical problem as the claimed invention".[77] Similarly, according to EPO examination guidelines, the closest prior art is "that which in one single reference discloses the combination of features which constitutes the most promising starting point for an obvious development leading to the invention".[78] This piece of closest prior art is determined based on the perspective of a person of ordinary skill in the art prior to the priority date of the application in question.[79]

Second, the objective technical problem must be determined. Distinguishing features between the claimed invention and the identified closest part art are identified.[80] The technical effect resulting from those distinguishing features is used to determine the technical problem, which may be different from what the claimed invention's application presented as the problem to be solved.[81]

Finally, the invention must not be obvious to a person skilled in the art based on the closest prior art and the objective technical problem. In particular, teaching in the prior art must be sufficiently clear such that it would prompt one skilled in the art to modify the prior art to achieve the claimed invention.[82] The ability of one skilled in art is measured as their ability prior to the priority date of the claimed invention to prevent hindsight bias.[83]

5.2.2 Differing Interpretations of Persons Ordinarily Skilled in the Art

Interpretation of the term "person of ordinary skill in the art" differs between Europe and the USA. Unlike in the US courts following the *KSR* opinion, European courts are unlikely to grant substantial creativity to a person of ordinary skill in the art.

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[75] *See*, *e.g.*, Case T-0159/95 (Bd. App. EPO 2000).

[76] *See* Guidelines for Examination in the EPO, Part G—Chap. VII-3 (June 20, 2012).

[77] Case T1203/97.

[78] *See* Guidelines for Examination in the EPO, CVII, 5 (June 20, 2012).

[79] *See* Guidelines for Examination in the EPO, CVII, 5.1 (June 20, 2012).

[80] *See* Guidelines for Examination in the EPO, CVII, 5.2 (June 20, 2012).

[81] *Id.*

[82] *See* Guidelines for Examination in the EPO, CVII, 5.3 (June 20, 2012).

[83] *Id.*

6 Best Mode

The best mode requirement requires the patentee to disclose the best mode of practicing the invention that is known at the time of filing. It is a requirement that is particular to US patent law.

6.1 United States

In the USA, the patentee must disclose the best mode of practicing the invention. This requirement is codified in the first paragraph of 35 U.S.C. § 112, stating that the specification "shall set forth the best mode contemplated by the inventor of carrying out his invention".[84] The best mode is determined by the inventor at the time of filing and must be sufficient to enable a person of ordinary skill in the art to practice that best mode.[85] The requirement exists to ensure adequate disclosure by the patentee to the public in exchange for the patentee's exclusive patent term.[86] In other words, the best mode requirement is used to prevent the patentee from keeping the best mode secret from the public, because this would allow the patentee to extend their benefit beyond the term of the patent.

Best mode remains a patentability requirement in US patent law, despite the implementation of the AIA.[87] This requirement has changed, however, for purposes of defenses in patent validity or infringement proceedings. Specifically, the lack of a best mode in a patent specification may no longer result in a claim being cancelled, held unenforceable, or held invalid.[88] This change was made, in part, to accommodate foreign applicants and to harmonize US patent law with other patent systems, because the best mode requirement is alien to patent regimes outside of the USA.[89]

6.2 Europe: No Requirement

In Europe, the patent applicant is not required to disclose the best mode of practicing the invention. Instead, European enablement requirements mandate at

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[84] 35 U.S.C. § 112 (2004).

[85] *Eli Lilly & Co. v. Barr Laboratories Inc.*, 251 F.3d 955, 963 (Fed. Cir. 2001).

[86] *See*, *e.g.*, *Eli Lilly & Co.*, 251 F.3d at 963.

[87] Leahy-Smith America Invents Act (AIA), Public Law 112–29, 125 Stat. 284 (September 16, 2011).

[88] 35 U.S.C. § 282 (2011).

[89] *See*, *e.g.*, *Perspective on Patents*: *Harmonization and Other Matters*: *Hearing Before the Subcomm. on Intellectual Property of the Comm. on the Judiciary*, 109th Cong. 182 (2005).

least one method of practicing the invention, although that method need not be the best method contemplated by the applicant.[90]

7 Enablement

Enablement is a patentability requirement that is common to both the USA and Europe. Generally, it requires that the patent disclosure be sufficiently detailed to allow a person of ordinary skill in the art to practice the claimed invention.

7.1 United States

Enablement is an explicit patentability requirement in the USA. Enablement is codified in the first paragraph of 35 U.S.C. § 112, requiring the specification to enable "any person skilled in the art… to make and use" the invention.[91] Disclosure sufficient to enable one mode of practicing the invention is not necessarily sufficient. Rather, the full scope of the claimed invention must be enabled.[92] This requirement prevents an inventor from acquiring enforceable patent rights that are broader than what would be disclosed to the public, for example by merely enabling one of many claimed embodiments.

7.1.1 Enablement Factors

The inquiry into whether a patent application's enablement is sufficient relies upon several factors. These factors may include, but are not limited to: (1) the quantity of experimentation necessary; (2) the amount of direction or guidance presented in the specification; (3) the presence or absence of working examples of the invention; (4) the nature of the invention (i.e., more complex inventions require greater enablement); (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art (i.e., how much may be extrapolated); and (8) the breadth of the claims.[93] For example, if little experimentation would be necessary to practice the claimed invention, then the burden of enablement on the patentee will be lower than for an invention wherein significant experimentation would be required to practice that invention.

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[90] European Patent Convention art. 83, 14th ed. Available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar83.html.

[91] 35 U.S.C. § 112 (2004).

[92] *See*, *e.g.*, *MagSil Corp. v. Hitachi Global Storage Techs.*, 687 F.3d 1377, 1381 (Fed. Cir. 2012).

[93] *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

7.1.2 Use of Post-Filing References

In the USA, post-filing references may be used to support enablement. Specifically, publications that are published after the filing date of a patent application may be used to determine whether the patent application's disclosure was sufficiently enabled at the time of filing.[94] For a patent applicant to rely on a post-filing reference, however, the applicant must file either an affidavit or a declaration.[95] The affidavit or declaration must assert that the post-filing reference establishes that the patent application was enabling for a person of ordinary skill in the art at the time of filing.[96]

7.2 Europe

In Europe, the patentability requirement "sufficiency of disclosure" is analogous to enablement and is codified by Article 83 of the EPC. Article 83 states that the "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".[97] The EPO Board of Appeals has explained that, based on the patent application's specification and the knowledge of a person ordinarily skilled in the art, the person ordinarily skilled in the art must be able to practice the full scope of the invention without undue burden.[98]

The EPC requires, if appropriate, at least one example for practicing the claimed invention.[99] Generally, broader claims will require multiple examples for the application to have sufficiency of disclosure. Conversely, the sufficiency of disclosure for narrow claims may be satisfied by a single example. Unfortunately, decisions from the EPO Board of Appeals concerning sufficiency of disclosure have been somewhat unpredictable. Therefore, the applicant may be best served by erring on the side of caution by disclosing multiple examples to ensure sufficiency of disclosure.

The EPO may object to a patent application for lack of sufficiency of disclosure, however, "[o]nly if there are serious doubts, substantiated by verifiable facts".[100] Broad claims do not necessarily render an application insufficiently disclosed;

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[94] *Gould v. Quigg*, 822 F.2d 1074, 1078 (Fed. Cir. 1987).

[95] 37 C.F.R. § 1.132.

[96] *See*, *e.g.*, *In re Brandstadter*, 484 F.2d 1395 (CCPA 1973).

[97] European Patent Convention art. 83, 14th ed. Available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar83.html.

[98] Case No. T 19/90 at 12 (Bd. App. EPO 1990).

[99] European Patent Convention rule 27(e). Available at http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/r27.html ("describe in detail at least one way of carrying out the invention claimed using examples where appropriate and referring to the drawings, if any").

[100] *Hitachi, Ltd. v. DaimlerChrysler AG*, No. T 0063/06 at 7 (Bd. App. EPO 2008).

instead, the focus is on whether a person of ordinary skill in the art would be able to practice the invention.

7.2.1 Use of Post-Filing References

Patent applicants in Europe may also rely on post-filing references to support enablement. The EPO Board of Appeals, for example, has stated that "post-published documents may constitute evidence that the invention was indeed reproducible without undue burden at the relevant date".[101] This holds true where the disclosure is deemed "credible".[102] Where no evidence is produced to support the use of a claimed invention, the EPO is unlikely to allow post-published documents to cure an insufficient disclosure.[103] Unlike the USPTO, however, the EPO does not require an accompanying affidavit or declaration.

8 Patent-Eligible Subject Matter

Not all types of inventions are patentable; both the USA and Europe carve out patent-eligibility exceptions. In recent years, the disparate patent systems of Europe and the USA have experienced a degree of harmonization regarding the scope of what may be patented, although differences remain.

8.1 United States

8.1.1 Patent-Eligible Subject Matter

In the USA, the law governing patent-eligible subject matter is codified in 35 U.S.C. § 101.[104] It specifically provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title".[105] Therefore, the four explicit categories of patent-eligible subject matter are as follows: (1) processes, (2) machines, (3) manufactures, and (4) compositions of matter.

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[101] Case T1262/04 at 6 (Bd. App. EPO 2007).

[102] *Id.*

[103] *See*, *e.g.*, Case T1329/04 (Bd. App. EPO 2005) (where no evidence was presented that a steroid hormone could be used as claimed in the application).

[104] 35 U.S.C. § 101 (2004).

[105] *Id.*

Processes

In the USA, processes are patent-eligible subject matter. The machine-or-transformation test is an analysis that was used by the courts to assess whether such a process is patent eligible; according to the test, the process must either be tied to a particular machine or apparatus or transform a particular article into a different state or thing.[106] In a recent decision, however, the Supreme Court held that the analysis for whether a process is patent eligible is not limited to the machine-or-transformation test.[107] The Supreme Court, however, did little to articulate alternative analyses, resulting in continued use of the machine-or-transformation test by the lower courts.[108]

Biotechnology

The USA has taken an expansive view to the patentability of biotechnology, driven in large part through the Supreme Court's decision in *Diamond v. Chakrabarty* in 1980.[109] In *Chakrabarty*, the patent applicant developed a bacterium capable of breaking down crude oil and subsequently appealed the USPTO's decision that living things were not patent-eligible subject matter.[110] The Supreme Court declared that patent-eligible subject matter may "include anything under the sun that is made by man", classifying Chakrabarty's bacterium as a "manufacture" or "composition of matter" within the meaning of 35 U.S.C. § 101.[111] This broad view of patent eligibility has allowed the USA to be at the forefront of biotechnology development for the past three decades.

Business Methods and Software

In the USA, business methods are also patentable. In 1998, this was affirmed by the Federal Circuit, which held that a "method of doing business" is not non-patent-eligible subject matter, as long as a "useful, concrete, and tangible result" is provided.[112] The courts, however, have struggled to provide clear guidance on how to determine whether a business method claim is patent eligible. In 2010, for example, the Supreme Court rejected the Federal Circuit's exclusive use of the

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106 *See In re Bilski*, 545 F.3d 943, 954 (Fed. Cir. 2008) (en banc).

107 *Bilski v. Kappos*, 130 S.Ct. 3218, 3231 (2010).

108 *See, e.g., Classen Immunotherapies, Inc. v. Biogen Idec*, 659 F.3d 1057 (Fed. Cir. 2011).

109 *Diamond v. Chakrabarty*, 447 U.S. 303 (1979).

110 *Id.* at 305.

111 *Id.* at 309.

112 *State Street Bank and Trust Company v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (Fed. Cir. 1998).

machine-or-transformation test.[113] Unfortunately, the Supreme Court failed to articulate an appropriate test, instead rejecting the business method patent as non-patent eligible on the grounds of being an abstract idea.[114]

Software is also patentable, despite the availability of copyright law as an additional form of intellectual property protection. As early as 1972, the Supreme Court weighed in on the subject, explicitly not precluding patent protection for software.[115] In 1981, the Supreme Court went a step further, stating that "a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a… computer program".[116] Today, software patents are routinely granted provided that they do not embody non-patent-eligible subject matter.

8.1.2 Non-patent-Eligible Subject Matter

Certain subject matter is non-patent eligible in the USA, despite the seemingly broad language of 35 U.S.C. § 101. Three broad court-created categories of non-patent-eligible subject matter include (1) the laws of nature, (2) physical phenomena, and (3) abstract ideas.[117] Examples of these three categories are the theory of relativity, a mineral, and a purely mental step, respectively. For example, in a recent Supreme Court decision, a process for correlating a patient's blood test with the patient's health was considered to impermissibly embody laws of nature[118]; therefore, the patent was held to cover ineligible subject matter.

8.2 Europe

8.2.1 Patentable Subject Matter

In Europe, the law expressly discloses requirements for patentable subject matter. These requirements of patentable subject matter are codified in Article 52 of the EPC,[119] which provides that "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and

[113] *Bilski*, 130 S.Ct. at 3231.

[114] *Id*.

[115] *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972). ("It is said that the decision precludes a patent for any program servicing a computer. We do not so hold.").

[116] *Diamond v. Diehr*, 450 U.S. 175, 187 (1981).

[117] *Bilski*, 130 S.Ct. at 3225.

[118] *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012).

[119] European Patent Convention art. 52, 14th ed. Available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar52.html.

are susceptible of industrial application".[120] Therefore, patentability in Europe requires: (1) novelty, (2) an inventive step, and (3) industrial application.

Novelty

As described above, novelty in Europe is essentially the same as in the USA, albeit with a few differences. In Europe, prior art is examined as of the time an application is filed. This prior art is more inclusive than in the USA, however, and includes "everything made available to the public by means of a written or oral description [in any language], by use, or in any other way" before the application was filed.[121] Whereas the USA has certain exceptions and grace periods, in Europe if the information is disclosed to any member of the public, the disclosure can be enough to destroy the application's novelty provided that the person to whom the information was disclosed is legally free to disclose that information to others.

Inventive Step

As described above, the requirement of inventive step is the equivalent of the non-obviousness requirement in the USA. Unlike in the USA, however, Europe employs the problem and solution approach in a three-part inquiry.[122] First, the closest state of the art is identified, which is then used to determine the objective technical problem addressed by the invention, and finally, it is determined "whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person".[123]

Industrial Application

Industrial application is the third patentability requirement for applications in Europe. In Article 57, the EPC provides a broad, vague definition of industrial application, stating that "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture".[124] The EPO has provided some clarification on this definition such that an application's description should "indicate explicitly the way in which the

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[120] *Id.*

[121] European Patent Convention art. 54(2), 14th ed. Available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar54.html.

[122] *See*, *e.g.*, Case T-0159/95 (Bd. App. EPO 2000).

[123] *See* Guidelines for Examination in the EPO, Part G—Chap. VII-3 (June 20, 2012).

[124] European Patent Convention art. 57, 14th ed. Available at http://www.epo.org/law-practice/legal-texts/html/epc/2010/e/ar57.html.

invention is capable of exploitation in industry".[125] The EPO states, however, that industrial application will usually be self-evident except for certain claimed inventions, such as "methods of testing" and gene sequences, where this requirement is more strictly enforced.[126]

8.2.2 Patent-Eligible Subject Matter

European patent law clearly establishes categories of non-patent-eligible subject matter. These categories include: (1) discoveries, scientific theories, and mathematical methods; (2) aesthetic creations; (3) schemes, rules, and methods for performing mental acts, playing games or doing business, and programs for computers; and (4) presentations of information.[127] While some of these categories are quite similar to the categories of non-patent-eligible subject matter in the USA, such as scientific theories, the exclusion of software and business method patents is a notable difference.

[125] *See* Guidelines for Examination in the EPO, Part F—Chap. II-4 (June 20, 2012).
[126] *Id.*
[127] *Id.*

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Dr. Ulrich Storz was born in 1969 in Muenster. He graduated in Biology at the University of Muenster in 1998, where he received his PhD in 2002. He is author and co-author of several scientific publications in the field of biology and biophysics as well as of several publications in the field of intellectual property. He passed the German Patent Bar Examination in 2005. Since 2005, he has been admitted to practice as European Trademark Attorney at the European Trademark Office (OHIM). In 2006, he has been registered in the list of representatives before the European Patent Office.

Main practice areas in the field of Intellectual Property Law include Patent Prosecution, FTO, and Patent Infringement, as well as Patent strategies, especially in the Life Science field (i.e., Biotechnology, Biophysics, Biochemistry, Microbiology). One of his preferred fields of expertise is therapeutical antibodies. Ulrich is involved in some of the major antibody opposition cases pending at the EPO.

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SpringerBriefs in Biotech Patents, DOI: 10.1007/978-3-642-41293-6,

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He deals with technical issues of Patent Law and the Law on Employee Inventions across various areas of science. These include in particular patent infringement and vindication procedures. A special focus of his advice is the field of health care technology. He has considerable experience in drafting R&D cooperation agreements and also deals with issues of musical copyright.

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He clients benefit from his consultative approach, which focuses on educating clients on various aspects of patent law. He has taught several patent law classes and presented numerous seminars to both local and national audiences.

Representative technologies include DNA and protein therapeutics, biomarkers, genetic engineering, transgenic animals, gene therapy, molecular and cellular biological screening assays, vaccines, peptide/protein therapy and diagnostics, cloning fermentation, methods of nucleic acid amplification, and various biotechnical research tools. He also prepares non-infringement, invalidity and freedom-to-operate opinions, and negotiates and drafts license agreements for a variety of clients.