

Global Patent Prosecution

2023

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Patent Prosecution is an indispensable reference tool for IP owners, providing an overview of the hottest issues they should be aware of when securing effective patent protection in key markets around the world.

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Brief introduction of utility models

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SOME ESSENTIAL ASPECTS OF UTILITY MODEL PATENT IN CHINA

China grants three types of patents: invention, utility model and design. Of these, the utility model patent is not granted in some other jurisdictions. In 2021, China saw more than 2.85 million applications filed and more than 3.12 million patents granted for utility models (www.cnipa.gov.cn/col/col94/). The statistics indicate that the possibility of procuring utility model patents in China makes it an attractive jurisdiction. In addition, more utility model patents inevitably lead to more litigation. Therefore, it is essential for multinational companies to understand the advantages of utility model patents and their challenges. To this end, this article will briefly explain some essential aspects of the utility model patent under Chinese Patent Law.

DEFINITION OF UTILITY MODEL

Chinese Patent Law defines a 'utility model' as any new technical solution relating to shape or structure, or their combination, of a product that is fit for practical use. Therefore, as far as the legislative purpose is concerned, the utility model patent offers protection for any improvement in shape or structure, or their combination, of a product.

The shape of a product refers to the shape of and space occupied by the product that can be observed from the outside. Improvements relating to the shape of a product may relate to the three-dimensional or the two-dimensional shape of the product.

The structure of a product refers to the arrangement, organisation and interconnected nature of each part of the product. A product may have either a mechanical structure or a circuit structure. The mechanical structure refers to the relative position relationship, coupling relationship and necessary mechanical matching relationship, among others, between the components or parts that comprise the product. The circuit structure refers to the fixed connection relationship among the components or devices that comprise the product.

ELIGIBLE SUBJECT MATTER FOR A UTILITY MODEL PATENT

According to the definition of utility model, the eligible subject matter for a utility model patent must be products that, at least, feature improvements relating to their shape or structure. The products must be objects manufactured by an industrial process, with definite shape and structure, occupying a certain space. Not all processes are eligible for a utility model patent.

For a product without a fixed shape, such as a substance or material in a gaseous, liquid, powder or particle form, its shape cannot qualify it as a utility model. However, products without a fixed shape are not categorically excluded from the patent protection for utility models. As expressly indicated in the Guidelines for Patent Examination of the Chinese Patent Office (the Guidelines), a product may have a technical feature relating to a non-fixed-shape substance, such as a substance in a gaseous, liquid, powder or particle state, provided that the feature of the product is structural. This is a feasible way to pursue a utility model patent for a product without a fixed shape. Take, for example, a product relating to a disinfectant in liquid state. The claim for a utility model patent may be related to the product possessing another feature that has a shape, such as a container with a specific shape that contains and, thus, distinguishes the disinfectant, or the feature, for example, that the disinfectant has been transformed into a solid form of a specific shape that constitutes an improvement relating to the shape of the product over the prior art.

In addition, as expressly indicated in the Guidelines, a composite layer such as a coating may be regarded as the structural feature of a product. Therefore, a utility model patent can be granted for a product if its improvement of the prior art relates to the following features:

- the product has a composite layer on at least part of it, while the prior art product did not on the same part; or
- the product has a composite layer on part of it and this has a different structure to that of the prior art's composite layer (eg, thickness of the layer and number of sub-layers).

For a composite layer to be eligible for a utility model patent, however, there is one confusing issue that needs clarification: the chemical composition of a composite layer cannot constitute the structural feature required for a utility model claim. As a result, a product is not eligible for a utility model patent if its improvement over the prior art concerns the chemical composition of the composite layer.

PREPARATION AND EXAMINATION OF APPLICATIONS FOR UTILITY MODEL PATENT

The application documents for a utility model patent must include a description, an abstract and appending drawings, and the claims. Thus, there is no substantive difference in the preparation of the application documents between a utility model and an invention patent.

At present, the examination system of 'preliminary examination plus evaluation report' is applied to the grant and subsequent enforcement of utility model patents. That is, only preliminary examination is required for the grant of a utility model patent, while granting an invention patent entails substantive examination in addition to preliminary examination.

The preliminary examination of a utility model patent application is focused on whether:

- the utility model is contrary to the law or social morality; is detrimental to the public interest; or falls under subject matter ineligible for patent protection;
- the application documents (including the request, description and claims) of the patent meet the formal requirements;
- the utility model falls outside the statutory definition of 'utility model';
- the utility model lacks novelty or practical applicability; and
- the utility model fails to meet the enablement or support-by-description requirement.

Such an examination system ensures that a utility model patent can be issued quickly, generally within six to eight months of filing. However, it inevitably means that some low-quality utility model patents are granted, of which some should be non-patentable for obviousness, even though a lower inventiveness standard is applied to utility models than inventions under Chinese Patent Law.

An increasing number of low-quality utility model patents has given rise to growing concerns over patent abuse, especially in some emerging industries. Recently, a member of the Chinese People's Political Consultative Conference presented the proposal "To Regulate the Market Order of Lithium Battery Industry and Avoid Malicious Competition by Abusing 'Problematic Patents'", explicitly expressing such concerns over the abuse of low-quality utility model patents in the lithium battery industry. The Chinese Patent Office replied to the proposal, stating that stricter standards would be put in place for the primary examination of applications for utility model patents, including the examination of *prima facie* obviousness

of a utility model. Further, the Chinese Patent Office suggested adding the examination of *prima facie* obviousness to preliminary examination, among other things, in the proposed draft amendment to the Implementing Regulations of the Patent Law, showing its resolution to actively reform the utility model patent system.

ENFORCEMENT OF A UTILITY MODEL PATENT

Under the 'preliminary examination plus evaluation report' system, after a utility model patent is granted, the patentee or an interested party involved in a dispute over patent infringement may request that the Chinese Patent Office issues an evaluation report of patent right, which will list relevant prior art references and set forth examination opinions on the patentability (ie, novelty and inventiveness) of the utility model. In patent infringement litigation, the evaluation report is required to be submitted as a preliminary evidentiary document. If the report shows unfavourable opinions on the patentability of the utility model patent-in-suit, it is highly likely that the judge will suspend the patent infringement lawsuit, awaiting the outcome of the administrative proceedings before confirming the validity of the patent-in-suit. China adopts a split system (similar to the German patent system), under which patent infringements are determined by courts in civil proceedings, while invalidity challenges are heard by the China National Intellectual Property Administration's Patent Re-examination and Invalidation Department and then reviewed by the specialised courts in administrative proceedings.

Except for the evaluation report, the enforcement of a utility model patent is substantially the same as an invention patent. In particular, the liabilities and remedies for infringement of an invention patent and a utility model patent are substantially the same, including pretrial and permanent injunctions, preservation measures and the compensation standard for damages. To date, the highest damages for patent infringement awarded by Chinese courts is Rmb330 million in *CHNT v Schneider Electric SA*. In this case, CHNT, a domestic manufacturer for electrical switches and sockets, sued Schneider Electric SA for infringing its utility model patent, claiming Rmb330 million in patent infringement damages, which was then supported by the district court.

Another controversial issue concerns the construction of a utility model patent claim containing a feature that does not relate to the shape or structure, or their combination, of a product (non-structural feature), such as a feature related to the materials of the product or a functional feature that defines part of the product by what the part can do. With such a non-structural feature, the question is how to consider its role in the evaluation of novelty and inventiveness and in the determination of patent infringement. The Supreme Court basically addressed this issue in *Hu Xuehui v Yue Xia* by holding that:

- any non-structural feature of a utility model patent claim should have a limited impact on the determination of patent infringement, and functional features should be narrowly interpreted as limited to the embodiment of structural features indispensable for implementing the function as disclosed in the description; and
- any non-structural feature should not be treated as a substantive feature that novelty and inventiveness of the utility model relies upon.

Be very cautious when drafting a utility model patent claim and introducing a functional feature. The best practice is to pursue an invention patent rather than a utility model patent



if it is indeed necessary to include functional features in the patent claim to broadly claim your invention.

UNIQUE DOUBLE FILING STRATEGY IN CHINA

Chinese Patent Law provides that an applicant may file applications for a utility model patent and an invention patent on the identical subject matter on the same day, and the applicant may later abandon the utility model patent just before the invention patent is granted to avoid double patenting. This provisions allows for the unique strategy usually referred to as 'double filing'.

The advantages of the double filing strategy are clear. If an applicant files on the same day two applications for an electrical device, one for a utility model patent and one for an invention patent, then the utility model patent will be granted within approximately six months of the filing date. The patentee can enforce the utility model patent immediately despite the pending application for the invention patent. By enforcing the utility model patent, the patentee may exclude its competitors from making and using the patented electrical device. Thus, the quickly granted patent right shall be the most desirable as the patented electrical device may be a type of product that has a short product life cycle. The patentee can maintain and enforce the patent right for the utility model until he or she abandons the utility model patent before the grant of the invention patent. It is clear that the double filing strategy can enable the quickly granted utility model patent to fill the gap of protection before the grant of the invention patent, whose application process generally spans more than two years.

Because of the above-mentioned advantages, the double filing strategy has been extensively used to patent those products that have a relatively short life cycle or may be easily copied and marketed. To prevent too many double filings, the Chinese Patent Office is now:

- not starting the substantive examination of any application for an invention patent filed under the doubling filing system until the end of four years from the filing date; and
- barring such an application for an invention patent from any expedited examination procedure.

Finally, the double filing strategy can apply for patent applications under the Paris Convention but not patent applications under the Patent Cooperation Treaty.





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EPO opposition procedure

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Summary

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The EPO allows applicants to seek patent protection in up to 44 countries via a single, centralised patent application process. As part of this streamlined offering the EPO also operates a centralised procedure by which third parties can seek invalidation of patents granted by the EPO. This process is referred to as 'opposition'. The ability to attack a granted patent centrally with a view to limiting or revoking it in all designated countries simultaneously is extremely efficient. It is therefore no surprise that the opposition system is well used by businesses wanting to manage risk against third-party patents.

Any person wishing to object to a patent granted by the EPO has a nine-month window, starting from the publication of the grant of the patent, in which to file an opposition. The costs associated with bringing an opposition are typically an order of magnitude lower than performing a patent challenge before a national court of a single country. As such, EPO oppositions are a very cost-effective method of invalidating patents in Europe.

HOW DO THEY WORK?

From filing a notice of opposition to a final decision, for a typical case, the EPO aims to dispose of cases within 15 months. The definition of a 'typical case' is unclear but may be assumed to involve:

- · a single opponent;
- no reliance on witness testimony or evidence of prior use;
- · no extensive translation requirements; and
- · using fewer than 10 primary prior art references.

More complex oppositions may take longer. If corresponding proceedings have been instigated in the national courts, then it is also possible to request acceleration of opposition proceedings.

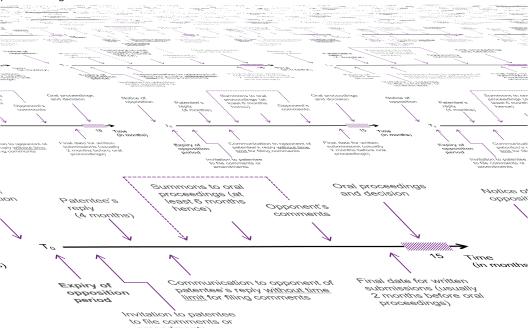


Figure 1: EPO opposition timeline

The opposition process is predominately paper-based and front-loaded. As far as possible, an opponent should include all the evidence and arguments that they wish to rely on in their notice of opposition. This includes all the grounds on which the opponent seeks revocation and the extent to which the opponent desires revocation. Similarly, the patentee is required to provide all the evidence and arguments that they wish to rely on in their reply to the notice of opposition. A final deadline for written submissions is set by the EPO, usually two months before an oral hearing is scheduled to decide the matter.

The main grounds on which patents are typically attacked include:

- added subject matter (the claimed invention was not disclosed in the application as originally filed);
- lack of sufficiency (the invention cannot be reproduced);
- lack of novelty (the invention was already known when the application was first filed);
 and
- lack of inventive step (the invention would have been obvious at the time of filing).

All opposition proceedings are open to the public.

The oral proceedings held by the EPO for oppositions typically last only one day (on rare occasions, two days) and a decision is handed down at the end of the day (and formalised in writing a month or so later).

Decisions reached at first-instance opposition hearings can be appealed to the EPO Board of Appeal. The appeal process is not as streamlined as the opposition procedure, and the current backlog of cases before the board means that overturning or upholding decisions can take a long time. Referring to the EPO Board of Appeal annual report 2020, 90% of appeal cases were disposed of within 60 months.

ORAL PROCEEDINGS

As with the patent examination process (or 'patent prosecution') before the Examining Division, cases at opposition are heard by a trio of examiners who make up an Opposition Division. One of the members of the Opposition Division will be the primary examiner, who will have been responsible for the patent while it was undergoing prosecution. A secondary examiner and a chair, who were not involved in the case's prosecution, are also present. All three are highly experienced examiners skilled in the technical area to which the patent relates.

Although the language of the procedure is always that of the patent under challenge, submissions at hearings may be made in any EPO language (English, French or German) and interpreters are provided by the EPO on request, usually where multiple opponents are involved. Oppositions and appeals require a range of skills, including meticulous case analysis, drafting (of submissions and amendments) and oral advocacy. The key is to present the story that will underpin a winning case. This must be framed sensitively during the written procedure, using the best technical evidence available.

Ultimately, the patent will either be maintained (ie, as granted or in an amended form) or revoked in its entirety. This differs substantially from many national proceedings where the granted claims often cannot be amended but individual claims can be found valid or invalid.

Both the legal tests and the protocols governing when and how submissions may be made during opposition are unique to these proceedings. This is especially true regarding appeals following the introduction of the revised Rule of the Boards of Appeal, last updated on 1 April 2021. As such, it is vital to engage European patent opposition specialists in such matters.

Perhaps partly as a result of the covid-19 pandemic, the EPO has greatly increased its video conferencing capability to enable more hearings to be conducted remotely. This has been valuable for both opponents and patentees – reducing the cost of hearings and enabling more individuals to attend (both from the parties to proceedings and from the wider public).

DIFFERENCES COMPARED TO NATIONAL INVALIDITY PROCEEDINGS

Although the Opposition Division does have the power to issue costs awards against parties in certain circumstances (eg, where an abuse of process occurs), unlike many national invalidity proceedings, both sides typically bear their own costs. This prevents parties from outspending the other side to create the threat of a potentially excessive costs award.

Another important difference between national proceedings and EPO opposition proceedings is that, even if an opponent withdraws from an opposition, the EPO may nevertheless decide to continue with proceedings of its own volition. Accordingly, once the process has started, attempting to reach a settlement with the patentee is not necessarily straightforward.

In addition, unlike national proceedings, there is no disclosure requirement before the EPO. As such, this greatly simplifies the procedure and avoids the inadvertent publication of irrelevant, yet commercially sensitive, company information.

It is also worth emphasising that the EPO is solely concerned with the validity of patents, not matters of infringement.

RECENT CHANGES TO OPPOSITION PRACTICE

The biggest change to opposition practice has been the widespread adoption of remote video conference oral proceedings.

The Enlarged Board of Appeal recently ruled that oral proceedings before the Boards of Appeal can, during a period of general emergency impairing the parties' possibilities to attend in-person oral proceedings at the EPO premises, be held by videoconference even without the consent of the parties. While this ruling focuses strictly on appeals, it may be an indicator of the direction that opposition oral proceedings are heading.

More generally, the changes made to the Rule of Procedure of the Boards of Appeal now make it much more difficult for parties to submit new evidence, or even new arguments, into later proceedings if such things were not included at first instance (ie, before the Opposition Division). These changes reflect the attitude of the Boards of Appeal that appeal proceedings are not intended to be a 'second bite at the cherry' but an opportunity to correct errors in the referred decision, based on the arguments and evidence that were presented in the first instance. Accordingly, parties should ensure that everything that they could conceivably wish to rely on is included in opening opposition submissions, otherwise it may be off limits at appeal.

OPPOSITION STRATEGY

As with so many forms of contentious proceedings, it is important before embarking on an opposition to consider what a commercial success would look like in a given scenario. There is often a range of competing factors that must be balanced. For example, do you need to completely remove a patent from the landscape or is it sufficient to force the patentee to limit its patent in a particular direction? Knowing how far you need to limit a patent so as to avoid infringement ensures that efforts and costs are concentrated where they are most valuable.

From a wider business context, it should be considered how a patentee might react in reply to your opposition to their patent. Do you want them to know that you are the party objecting to their patent; or should the patent be attacked anonymously? Raising your head above the parapet might draw attention to your business and perhaps your own patent portfolio. That said, there might also be advantages to appearing on the patentee's radar.

It is advisable to be especially careful regarding what arguments are placed on file during opposition proceedings, particularly in sectors where there is a high degree of technical overlap between the products or processes of the parties. Failure to adhere to a consistent story where multiple parallel proceedings are pending can often undermine your own patent position.

ADDITIONAL BENEFITS OF THE OPPOSITION PROCEDURE

Because the EPO operates a high standard of examination, patents that survive the EPO opposition processes are likely to stand up well to scrutiny during national proceedings. Moreover, many jurisdictions look to the EPO on certain matters of case law, where the law may be more comprehensively developed. Examiners at the EPO also have a great deal of experience with patent matters and are generally well versed in the technology discipline to which they are assigned. Consequently, it is highly unlikely that the complexity of the technology in question will obscure the legal issues involved in a given determination. This can be advantageous because not all courts across Europe are equipped with a large body of technically trained judges.

Another benefit of the EPO opposition process is that parties can effectively file an opposition anonymously (provided they are not opposing their own patent). It is common practice for representatives to be identified as the opponent, masking their client's involvement. Given that many industrial sectors have complex, interdependent supply chains, it is not unreasonable for interested parties to avoid being labelled on an opposition out of a desire to avoid appearing antagonistic with respect to a particular patentee (who may be both supplier and competitor).

COMMENT

The EPO opposition process is a useful tool in the arsenal of businesses to help manage risk and problem patents across many jurisdictions in a single, cost-effective procedure. The system is relatively quick, well tested and cases are heard by experienced examiners with good technical knowledge.



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Software patent eligibility practice at the **EPO**

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In common with many patent offices around the world, some inventions that are implemented in software may be patented before the European Patent Office (EPO). In this article, we explore software patentability, covering why only some software inventions are patentable before the EPO, the requirements for an invention to be patentable and how patent practice before the EPO with respect to software inventions may evolve in the future.

The European Patent Convention (EPC) is the statute under which the EPO operates to determine the grant of European patents. The EPC defines that European patents shall be granted in all fields of technology but excludes a specific list of the subject matters considered inventions, which includes, *inter alia*, mathematical methods, methods for doing business and programs for computers. These exceptions from patentability have been described as relating to activities that do not aim for any direct technical result but are rather of an abstract and intellectual character. The exceptions from patentability are, however, limited in scope in that they only relate to "such subject-matter or activities as such".

As can be noted from the above references to technology and technical results, technical character is a requirement of an invention under the EPC, which was previously only implicitly required but which is now explicitly mentioned in Article 52 (1) EPC. To determine the patentability of an invention, particularly one that may relate to computer software, the EPO applies a two-hurdle approach. The first hurdle is to assess whether a claim relates to a non-invention falling within one or more of the excluded subject matters. The second hurdle involves consideration of whether the remaining requirements for a patentable invention are met, particularly that the invention is novel and has an inventive step. Thus, only the claimed subject matter with a technical character can be considered an invention, and to be a patentable invention it must also be novel and have an inventive step.

Here we see a parallel with US patent practice, in which there are also two patent eligibility hurdles to overcome, known as the Alice test. Here, the first hurdle is a test of whether the claimed invention involves a patent-ineligible concept. A patent-ineligible concept is one considered an "abstract idea", as determined by the US Supreme Court. If so, to then avoid rejection, there must be some elements of the claim relating to an inventive concept sufficient to transform the abstract idea into one relating to a patent-eligible invention. The inventive concept must be more than a recitation of a well-understood, routine, conventional activity. On the face of it, therefore, merely reciting in a claim generic computer features or activities such as 'processing' and 'receiving' will not be sufficient to transform the claim from one that is considered abstract to patent-eligible subject matter. In comparison to the EPO's two tests, the first difference between the EPO and US practices is that, under EPO practice, it is considered whether the claim as a whole avoids the exclusion of computer software as such, whereas at the United States Patent and Trademark Office (USPTO), it is assessed whether the claimed invention is patent ineligible. However, the second tests under both systems have more in common as both are looking for matter that is more than routine. According to our understanding, the test for eligibility under US practice is separate from the considerations of novelty and inventive step, although some cases recognise some overlap between these requirements; whereas under EPO practice, an inventive step over the prior art is only provided by matter with technical character.

At the EPO, every patent application is also examined with respect to novelty and inventive step, among other requirements. The inventive step requirement of the EPO corresponds with the requirement for non-obviousness of the USPTO. However, the inventive step

requirement differs in some aspects from the non-obviousness requirement of the USPTO, which is described below.

The first hurdle to overcome before the EPO is also a form of eligibility test but with a relatively low bar, only excluding subject matter that is entirely devoid of any technical character. A claim that includes any technical means is said to clear the first hurdle to be considered an invention. This test is often referred to as the 'any hardware' or 'any technical means' approach. This determination is made without reference to the prior art. Therefore, a first step to considering whether a claim is likely to be patentable before the EPO is to assess whether the claim refers to a technical entity, particularly hardware. In practice, it can often be surprising how many, particularly method, claims can be found at the initial prosecution stage that, on close inspection, do not refer to any hardware. One relatively easy way of ensuring that the first hurdle is cleared can be to recite a computer-implemented method. In other words, if any hardware such as a computer, storage or microprocessor is mentioned in the claim, then it will pass the first hurdle.

At the second hurdle, the requirement for an inventive step over the prior art is examined. The examination for inventive step is simultaneously subject to the limitation that only technical aspects of the claimed invention can be taken into account. In other words, any matter in the claim that is not considered technical cannot give rise to an inventive step over the prior art. Thus, at the European Patent Office, the test of whether the claimed subject matter fulfils the requirement of 'technicality' is assessed simultaneously with the evaluation of whether the subject matter of the patent application has an inventive step.

The EPO has developed a special process for assessing inventive step, which is referred to as the problem-solution approach. The problem-solution approach was modified by the EPO for assessing 'computer-implemented inventions' (CIIs), which is the term used by the EPO for inventions that are usually realised through software and that are colloquially called 'software patents'.

Under the modified problem-solution approach, features of the claim under examination are assessed as to whether they contribute to the solution of a technical problem. Only features of the claimed invention that provide such a technical contribution are considered. In some 'mixed-type' inventions, being a mix of technical and non-technical claim elements, non-technical features can be considered, such as pure software steps, but only if they contribute to the formulation of the technical problem solved by the invention.

During its existence, the EPO has twice reviewed its case law relating to CIIs in the form of decisions of its Enlarged Board of Appeal. The first decision (G 03/08) from 2010 contains an overview of previous case law on CIIs, which confirmed the two-hurdle test and did not make any changes to the EPO's approach going forward.

The second decision of the Enlarged Board (G 01/19) was issued in 2021 and concerns the patenting of computer-aided simulations. On the one hand, the principles of the first decision were confirmed and, on the other hand, specific comments were made on the legal problems that arise when patenting computer-aided simulations.

Computer-implemented simulations use a numerical model that is fed with input data and in turn produces data as an output indicative of the result of the simulation. Thus, data is processed without directly influencing the physical world. In this sense a computer-implemented simulation could be considered a purely mathematical process. As noted above, mathematical methods as such are excluded from patentability. One could,

therefore, come to the conclusion that computer-implemented simulations are in principle not patentable.

In this decision, however, the Enlarged Board of Appeal came to a different conclusion and stated that computer-implemented simulations are not fundamentally excluded from patentability. Instead, computer-implemented simulations can be patented if they relate to a technical invention according to the principles set out above.

The term 'technology' is not clearly defined in either the EPC or case law. Rather, the definition of 'technology' is left open so as not to exclude future technical developments from being patented. However, one can guided by what is not technical, which is excluded from patenting under the EPC (eg, mathematical methods, methods for doing business and computer programs).

For example, a mathematical solution of a differential equation is a mathematical method and, as such, cannot be patented. However, if the shape of a new antenna is described by this solution of the differential equation, and the properties of the antenna are thereby improved, then the resulting antenna is patentable, as it is undoubtedly a technical object. The essential step that led to the invention was the solution of the differential equation. However, this mathematical solution has a technical effect when applied to antennae. There are many solutions of differential equations that are unsuitable for antennae, but a technical contribution is provided by the solution of this differential equation as applied to an antenna. In European patent law, this is also a technical contribution that can be rewarded with patent protection if it is new and inventive.

This is a relatively simple example that clearly shows the difference between a pure mathematical method and technical subject matter relating to a mathematical method. However, there are also cases where it is much more difficult to determine whether this matter is technical in regard to European patent practice.

In the above-mentioned decision of the Enlarged Board of Appeal on computer-based simulations, an earlier Board of Appeal decision relating to 1/f noise was discussed in detail. The granted European patent arising from this decision relating to 1/f noise defines the simulation of 1/f noise for optimising electrical circuits. Here too, a mathematical procedure simulating 1/f noise is used to optimise a technical object in the form of the electrical circuit. Even if not every simulation automatically leads to a new design of an electrical circuit, the technical contribution was judged to be sufficient for the patent to be granted.

In its more recent decision, the Enlarged Board of Appeal clarified the protection of computer-assisted simulations to the effect that:

- the technical effect must be present over the entire scope of protection for the claimed invention; and
- the technical use of the simulation must be defined in the patent claim, although it may also be only implicitly present in the claim.

What does this mean for the 1/f noise example? The parallel US patent (US 6,795,840 B1) was granted with a claim very similar to the claim of the corresponding European patent. However, the limitation to electrical circuits is missing from the US claim. Here, a "computer programmed to process a method of determining sequences of random numbers of a 1/f

noise . . ." was patented. The description of the US patent also states that the simulation of the 1/f noise can also be used to predict "events on the financial markets".

According to the case law of the EPO, the US claim would likely be considered a purely mathematical method and a business method as such, both of which are excluded from patentability in Europe.

Thus, the claim of the US patent does not contain any indication of technical use as required by the EPO's Enlarged Board of Appeal. Moreover, the scope of protection of the US patent claim can be said to extend to applications in the financial sector, which are not technical in nature under European practice. Consequently, the US patent claim is not technical over its entire scope of protection, and the US patent would likely not be granted by the EPO. The definition of the technical use, namely the use for electronic circuits, is missing from the US claim.

Although this example concerns one claim that is likely to be unallowable before the EPO as not being technical over the claim's entire scope, following the Enlarged Board of Appeal's decision, we expect that more objections will be raised by the EPO against non-technical claims over part of their scope. As a result, applicants will need to reduce the scope of their claimed protection during prosecution such that only technical embodiments are covered by the claim.

Recent case law in the United States, however, increasingly states that the software in question must improve "computer functionality" (ie, improve computing speeds or reduce the amount of computing resources required) or perform computing tasks in an unconventional way. This is similar to the requirement that an invention must be technical. We have the impression that, at least historically, the patenting practice of software patents in the United States is somewhat more generous than at the EPO, but it is not as clear when software is patent-eligible. The distinction between technical and non-technical inventions at the EPO seems to be better defined and, thus, clearer, which provides applicants with more certainty prior to application.

The patentability of AI before the EPO continues to evolve, and the EPO has provided helpful guidance on this subject in the 2022 update to the Guidelines for Examination. To assist applicants in this area, an example has been introduced to the Guidelines relating to the patentability of a spray coating system that is novel by virtue of including a neuro-fuzzy controller using a neural network and fuzzy logic rules. It is discussed that computational models and algorithms are in themselves mathematical methods and are thus not considered technical for the assessment of inventive step. However, as the controller is used to adjust the parameters of a technical process in the form of a coating process, the neuro-fuzzy controller contributes to the technical character of the invention and, thus, can be considered in the assessment of inventive step.

Recently the EPO, along with other patent offices, considered the issue of whether an Al system can be an inventor in respect of a patent application. The applicant, Steven Thaler, filed a patent application for a food container that had apparently been devised by an Al system named DABUS, which was consequently named as the inventor. The European application was subsequently refused on the grounds that the EPC required an inventor to be a natural person. This requirement was confirmed by a Board of Appeal. However, the EPO indicated its potential openness to patenting inventions derived by Al technology by



indicating that the owner of a device may be designated as the inventor under the EPC, which shows some consistency with the equivalent decision before the UK Court.



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Sustainable agriculture, green technologies and IP in Brazil

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Summary

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INTRODUCTION

Since the beginning of the Anthropocene period, 75% of the Earth's land surface has been modified to attend demands mainly related to food and bioenergy (MEA, 2005) $^{[1]}$. According to a study $^{[2]}$ published in *Environmental Sciences*, the advances of technological and industrial development have strongly decreased the number of the underfed people and promoted economic growth.

However, the expansion of agricultural activity demands large amounts of materials such herbicides and fertilizers, which can seriously jeopardize not only the environment, but also health and safety of the local population. Moreover, inordinate expansion of agricultural activities expressively threatens biodiversity conservation due to deforestation practices carried out to increase production, as well as soil exhaustion to an irreversible degree.

In addition, the industrialization and expansion of agricultural systems accounts for up to 30% of the emissions of greenhouse gases (GHGs), mainly methane and nitrous oxide, which reportedly contributes to global warming, according to the United States Environmental Protection Agency (EPA)^[3]. The highest portion of the contribution to global warming comes from GHGs emission from livestock production, measured by carbon footprints (CF)^[4].

In view of an increasing demand of agricultural production of a growing global population, future sustainable land management requires understanding the delicate balance between production and conservation efforts while avoiding trade-offs.

Aiming to overcome such challenges, the World Government Summit published a report named "Agriculture 4.0 – The Future of Farming Technology". Agriculture 4.0 mainly focus on precision agriculture, internet of things (IoT) and the use of big data to develop efficient business models in view of the increasing demand of population growth whilst mitigating effects of climate change. The approach is based on the four pillars of agriculture, namely demographics, scarcity of natural resources, food waste and climate change.

Even though such advances may sound as state-of-the-art technology, today we are already diving into the era of Agriculture 5.0, which includes improvements in IoT technologies, as well as a new focus on emerging technologies, such as artificial intelligence (AI) and machine learning (ML) combined with large volumes of data aiming to an even more profitable and more sustainable agriculture.

BRAZIL: AN INTERNATIONAL AGRICULTURAL POWER

Agriculture is one of the main bases of the Brazilian economy from the beginnings of colonization to the 21st century, evolving from extensive monocultures to diversification of production. Considering the partial performances of the Brazilian economy and agribusiness, it is estimated that the sector's share will be around 25.5% in 2022, slightly below the 27.5% recorded in 2021, according to CEPEA (Center for Advanced Studies in Applied Economics^[5]). Gross Domestic Product (GDP) of the agricultural sector grew the most in the first quarter of 2021, according to recent data released on 1 November 2022 by the Brazilian Institute of Geography and Statistics (IBGE). The sector recorded 5.7% growth compared to the fourth quarter of last year and 5.2% compared to the same period in 2020. Furthermore, the sector was responsible for approximately US\$ 13.9 billion in volume of exports together with livestock in September/2022, representing an increase of 38.4% compared to the same period in 2021, according to data from the Secretariat of International

Relations of the Ministry of Agriculture, Livestock and Supply (SRI/Mapa^[6]). Agricultural production in Brazil is, therefore, one of the main factors responsible for the country's trade balance.

Over the last four decades, productivity has been the main driver of growth in Brazilian agriculture. For example, the sector grew, on average, 3.36% per year since the 1970's, according to the Ministry of Agriculture, Livestock and Supply^[7]. Additionally, since the 2000's, Brazil has led world agricultural productivity among 187 countries, according to a study by the Economic Research Service, an agency of the United States Department of Agriculture (USDA) shows, released in October/2022^[8].

According to USDA, the product of Brazilian agriculture grew 3.75% per year in the last six decades, only below China with a growth of 4.41% per year. The study was based on 162 crops, 30 types of animal and insect products and eight aquaculture products. The inputs are land, labor, capital, and materials. Considering the last 20 years, the productivity of Brazilian agriculture increased by 3.18% per year, the highest rate among the selected countries, according to CEPEA.

Productivity gains came mainly from investments in research, the adoption of new production systems, improvements in infrastructure, including roads and the flow of production abroad through ports in the North of the country and the increase in the port capacity of Paranaguá (PR) and Santos (SP), and appropriate agricultural policy instruments.

According to Peace Nobel Prize candidate Alysson Paolinelli [9], Brazil is a concrete example that science is capable of transforming realities. From the 1970s to the present days, the country has become an international agricultural power, responsible for feeding 800 million people in the whole world. The Brazilian Cerrado, once considered unproductive, is one of the highlights in agricultural productivity and accounts for 60% of national grain production. For Paolinelli, global mobilization among nations is essential to bring innovation and technology to the tropical countries in need thereof. "Where there is hunger and inequality, there is no peace. Agriculture is the basis of food security and world peace", highlighted the former minister.

CHALLENGES AND THE IMPORTANCE OF GREEN TECHNOLOGIES FOR A MORE SUSTAINABLE AGRICULTURE

Agribusiness has doubled the emission of greenhouse gases in the last 50 years, having an undeniable impact in global warming and land degradation. According to data from the Food and Agriculture Organization of the United Nations (FAO), this could increase by another 30% in the next 30 years ^[10].

Moreover, the United Nations (UN) estimates that the world population will reach 9.7 billion people by 2050^[11] At the same time, agriculture faces the challenge of feeding this growing number of inhabitants while avoiding further harm to biodiversity and environment. According to a report by the Population division from the United Nations^[12], it is estimated that the global food production must have an increase of approximately 70% to attend this demand.

Green technology, defined by the European Environment^[13] agency (EEA) as the application of environmental sciences for the protection and conservation of nature, natural space, or biodiversity, aiming to prevent or mitigate the negative impacts of human activity on the environment, presents itself to increase the productivity of agriculture and the sustainability

therein. The main goals of such technologies are regeneration, recycling, less waste, and the use of renewable energy sources, which are included in the concepts of Agriculture 4.0 and 5.0.

Therefore, the optimization of the relationships between agriculture and state-of-the-art technology is pivotal to meet the increasingly pressing demands. Accordingly, agriculture has become an innovative hotspot within the global R&D landscape. Basically, the agricultural and food production industry has evolved from convict workers and experiment farms, to innovations in agricultural implements, pest control, food science and digital agriculture; innovations which will be crucial in solving the global challenges of food production and sustainability [14].

In this context, one can highlight the following technical fields to be developed to achieve the desire sustainable outcomes:

- New value and supply chains, such as biorefineries producing protein feed, biochemicals, biofertilizers and bioenergy, are forecast to play an ever-increasing role [15].
- Advances in plant biology, genomics and breeding to potentially unlock additional genetic variability and improve the efficiency and feasibility of developing new crop varieties ^[16];
- Precision agriculture, to promote a management strategy aiming to improve the efficiency, productivity, quality, profitability and sustainability of agricultural production;
- Autonomous tractors to help solve farming labour shortages [17];
- Drones to help the farmers to increase crop productions and monitor crop growth for maximum outputs [18].
- Seed-planting robots to decrease dependence on human labor [19].

IP TO FOSTER GREEN INNOVATION

The innovative environment depends on a robust IP rights system to encourage more innovation and creativity by making sure inventors and creators get a fair reward for their work and can earn a living from it and also to protect the goodwill vested in brands^[20].

As any other technical filed, the sustainable agriculture may benefit from the IP rights since they can stop other people from copying or using their IP without their permission or, on the other hand, permit the patent licensing and technology transfer agreements of the new protected technologies to obtain royalties.

GREEN TECHNOLOGIES RELATED TO AGRICULTURE: A BIRD'S EYE VIEW IN BRAZIL

The Brazilian PTO (BRPTO) produced a study on green technologies related to agriculture, called "Technological radar - analysis on the patenting of technologies related to sustainable agriculture filed in Brazil" One of the insights is the picture of the major applicants and representative technologies in the field of Sustainable Agriculture.

Despite the importance of the agriculture in Brazil, the major applicants are still foreign, represented, in increasing order of case numbers, by Basf, Bayer, Dow Agrosciences, Pioneer Hi-Bred International, Syngenta, Monsanto, Deere & Company, E.I. Du Pont de Nemours,

CNH Industrial, The Climate Corporation, Embrapa, Evogene, FMC Corporation, Novozymes, Sumitomo Chemical Company and Precision Planting.

These 16 companies own 37% of patent applications in the field of green technologies for agriculture filed in Brazil. On the other hand, it is interesting to note that about 40% of patent applications are owned by applicants who have only 1 or 2 patent applications, which demonstrate a dispersion of applications in this field by several companies, universities, research institutions and even individuals.

PATENTABILITY IN BRAZIL: SOME CHALLENGES

Due to the impressive role of Brazil's agriculture for the world, companies whose businesses target this market surely consider keeping a strong patent portfolio in this country. It is pivotal that companies and patent attorneys be aware particularities related to Brazilian patent practice, some of them are pointed out below:

- The whole or part of natural living beings and biological materials found in nature even if isolated from it, or synthetically produced that have naturally occurring counterparts, with no way to distinguish them from natural ones are considered natural biological products, thus, not considered as invention. However, in the event the non-transgenic microorganism is encompassed by a composition, the protection is possible provided that the further components of the composition do not represent mere dilution (a "mere dilution" is when the solvent does not contribute to this final purpose). A further alternative is to claim a combination of microorganisms, considering that said microorganisms are not found or supposedly should not be found together in nature. Transgenic microorganisms on the other hand, can be protected.
- Essentially natural biological process (e.g., crossing, pollination, amongst others) are
 also not considered as inventions. However, processes that contain at least one
 technical step that has a decisive impact on the final result and that cannot be carried
 out without human intervention are considered an invention. In this sense, process
 using transgenic plants are liable of protection, in view of the intervention by the
 genetic engineering on the plants.
- The BRPTO has recently issued positive opinions regarding plants, part of plants and seeds coated with compositions, provided that the coating has a permanent character. In this sense, there is an indication of green flag for the possibility of protecting coated plants, even though articles 10 and 18 of Brazilian IP law pose prohibition on patentability of plants or parts thereof

There are also efforts to improve the national IP environment. For instance, bill 2056/2022 proposes significative changes in the Brazilian IP law by proposing changing the definition of "end of the examination" to be the date of the final, unappealable decision published by the BRPTO, allowing a longer timeframe for voluntary amendments and for filing divisional applications. Additionally, it also proposes a compensation mechanism for delays in the prosecution of patent applications, allowing up to 5 years of adjustment in the term of the patent.

EXPEDITING EXAMINATION: GREEN TECHNOLOGY FAST-TRACK PROGRAM

The BRPTO has successfully established in 2012 the "Green Patent" fast-track program for green inventions. The scope of Green Patent Program considers "green technology" as



the technologies directly applied to "alternative energies", "transport", "energy conservation", "waste management" or "sustainable agriculture".

Specifically related to the sustainable agriculture, the program focuses on the following subgroups:

- Reforestation techniques
- · Alternative irrigation techniques
- · Alternative pesticides
- Soil improvement (for instance: organic fertilizers derived from waste)

From the beginning of the program until now (November 2022), 1,202 requirements of participation were filed and 500 patents were granted.

However, differently from the list of major filing players in Brazil discussed above, the green patent program is still mostly used by national applicants, since 882 applications have Brazilian patent family. We understand there is room for foreign companies to explore more this fast track program in Brazil.

CONCLUSION

Sustainable agriculture is one of the most important areas of innovation nowadays both by pressure posed by the increasing demand for food production and for eco-friendly practices in view of the worrying environmental degradation of our planet. To foster green innovation, countries should promote a receptive and updated IP environment. Inventors need guarantees of returns on investments made in developing new technologies. Therefore, IPRs must provide the suitable necessary protection of inventions and promote their regulated use. Additionally, fast track programs should be stimulated aiming a reasonable duration of the IP procedures avoiding the mismatch between development, protection and use of new technologies.

Brazil is an important player in world's agriculture and companies whose businesses focus on technologies in the field must consider this country when deciding where to file and strengthen their patent portfolio. Green technologies are liable to participate in the Green patent fast track program. Also, due to Brazilian patent practice particularities, it is important that interested companies seek expert advice early with the aim to ensure that the most commercially relevant scope of protection for green technology inventions is ultimately obtained in Brazil.

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China: patent prosecution

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Summary

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HOW DO YOU GET A PATENT IN YOUR JURISDICTION?

Q: WHAT TYPES OF PATENT ARE GRANTED IN YOUR JURISDICTION, AND WHAT RIGHTS DO THEY CONFER ON OWNERS?

Three types of patents are granted in China: invention patents, utility model patents and design patents. For invention and utility model patents, they confer on the owner exclusive rights to stop others from manufacturing, selling, offering for sale, using or importing the patented product, and they stop others from using the patented process or using, offering to sell, selling or importing the product directly obtained by the patented process. For design patents, the exclusive rights include stopping others from manufacturing, selling, offering for sale or importing the patented product.

Q: WHAT INVENTIONS ARE ELIGIBLE FOR PATENT PROTECTION IN YOUR JURISDICTION?

In China, any inventions are eligible for patent protection except:

- · scientific discoveries;
- rules and methods for mental activities:
- methods for the diagnosis or the treatment of diseases;
- · animal and plant varieties;
- nuclear transformation methods and substances obtained in the process of nuclear transformation; and
- designs of two-dimensional printing goods, particularly their pattern or colour, or a combination of the two, which serve mainly as indicators.

Q: ARE THERE ANY SPECIFIC EXEMPTIONS TO PATENT ELIGIBILITY?

For processes used in producing animal and plant varieties, patent rights can be granted. Designs of two-dimensional printing goods are patentable if they do not mainly serve as indicators.

Q: ARE THERE TECHNOLOGY-SPECIFIC ELIGIBILITY ISSUES THAT APPLICANTS MUST NAVIGATE (EG, IN SOFTWARE, BUSINESS METHODS, AI, MEDICAL DIAGNOSTICS, PHARMACEUTICALS OR MEDICAL PROCEDURES)?

For inventions in the fields of software, business methods and AI, only those solving technical problems by employing technical solutions and achieving technical effects can be granted patent rights, whereas mere rules of activities or commercial rules cannot be granted patent rights. In addition, medium-storing computer programs are now patentable in China.

Q: WHAT ARE THE TIME AND COSTS INVOLVED IN SECURING A GRANTED PATENT? IS EXPEDITED EXAMINATION AVAILABLE? ARE REDUCED FEES AVAILABLE FOR CERTAIN APPLICANTS?

For invention applications, on average it takes 19 months for them to be approved after the substantive examination starts. For utility model and design applications, a patent can generally be obtained within 6 to 12 months of filing. The most popular expediting examination programme is the Patent Prosecution Highway. The Chinese patent system does not differentiate between small and large entities for foreign applicants in terms of fees, and thus, no reduced fees are available for foreign applicants.

Q: WHAT ARE ANY SPECIFIC REQUIREMENTS THAT A PATENT SPECIFICATION MUST MEET IN YOUR JURISDICTION?

In short, a patent specification should fulfil two important requirements in China:

- sufficient disclosure: the description should be detailed enough for a person skilled in the art to make the invention; and
- support for claims: the description should disclose adequate embodiments or examples to support a broad generalised claim.

Q: WHAT RULES GOVERN THE FILING OF PROVISIONAL APPLICATIONS, CONTINUATIONS OR CONTINUATIONS-IN-PART, DIVISIONALS, OR ANY OTHER SPECIAL TYPE OF APPLICATION?

In China, there are no provisional applications, continuations or continuations-in-part, and only divisional applications are available, which can be filed at any time before the close of the prosecution of the parent application as long as the divisional application does not go beyond the disclosures of the parent application. If unity of invention arises in the divisional application, it is allowable to derive a second-generation divisional application after the close of the prosecution of the parent application.

Q: WHAT DO APPLICANTS NEED TO KNOW ABOUT OFFICE ACTIONS AND PATENT EXAMINER INTERVIEWS?

For each office action, the applicant can respond by presenting arguments with or without amendments, but they cannot appeal the action to another authority unless a rejection is received. Currently, the examiner is encouraged and willing to conduct interviews with applicants or their agents by telephone to resolve formality issues or even discuss the patentability of the application to achieve grant as soon as possible. The applicant has four months to present the response for the first office action and two months for other subsequent office actions during the examination. Either deadline of four or two months can be extended by up to two months with surcharges.

Q: ARE THERE ANY RECENT EXAMINATION TRENDS THAT PATENT APPLICANTS NEED TO BE AWARE OF?

In recent years, the examiner has become more and more rational in using common knowledge to reject the inventive step of an application. Further, the applicant can request that the examiner provides written evidence of common knowledge if it is a key feature of the technical solution. The Chinese examiner will also check the prosecution history in other countries, particularly the EPO, USPTO, Japan Patent Office and Korean Intellectual Property Office, and is not willing to grant a broader scope of protection than other patent offices.

Q: IS THERE ANYTHING ELSE ABOUT THE PATENT FILING PROCESS THAT APPLICANTS SHOULD KNOW?

It is noteworthy that:

• in China the applicant may choose to delay the examination of an invention patent application for one, two or three years upon request of examination;

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for design applications, the choice of delayed publication for one, two or three years is available, and partial designs can be protected in China; and

 by using the Paris Convention route, the applicant may file an invention patent application and a utility model application at the same time to get quick protection for the utility model and get stable protection for the invention patent, while the applicant may only chose to enter a Patent Cooperation Treaty application into the Chinese national phase as either an invention or a utility model.

Q: IS UTILITY MODEL OR PETTY PATENT PROTECTION OR AN EQUIVALENT AVAILABLE IN YOUR JURISDICTION? IF SO, HOW DOES THE SYSTEM WORK AND UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE USING IT?

Utility model patents are available in China and can be protected for 10 years. Utility model patents only protect the improvement of the structure or configuration of the product, and cannot protect the method or process. A utility model patent can be obtained after preliminary examination and is not subject to substantive examination. However, the examiner is stricter now than in previous years and often challenges patentability by quickly searching and citing references if they believe the application is obviously not new or inventive.

WHAT ARE THE MAJOR ADMINISTRATIVE PROCEDURES IN YOUR JURISDICTION?

Q: HOW CAN APPLICANTS APPEAL PATENT OFFICE DECISION?

If the applicant receives a decision of rejection issued by the Chinese National Intellectual Property Administration (CNIPA), he or she may file a request for re-examination with CNIPA's Department of Patent Re-examination and Invalidation within three months of receipt of the decision of rejection. The documents to be filed shall comprise the request for re-examination, arguments, necessary evidence, procedural documents and possibly amendments, including power of attorney.

Q: ARE OPPOSITIONS AVAILABLE PRE-GRANT OR POST-GRANT? WHAT RULES GOVERN STANDING TO OPPOSE A PATENT AND THE OPPOSITION PROCESS?

There is a quasi-pre-grant opposition in China called 'third-party observations', which is an ex parte process. The Chinese Patent Law allows the public to file third-party observations together with evidence and reasoning against an invention application after it is published and before it is granted. However, these third-party observations are provided only for the examiner's reference, and the examiner is not obliged to respond or follow-up on these observations.

The post-grant opposition in China is called an 'invalidation request', which is an *inter partes* process. After the patent is granted, anyone holding that the patent does not comply with the provisions of the Chinese Patent Law can file a request for invalidation before the CNIPA. The patent that is announced as invalid after the invalidation process is deemed non-existent from the very beginning.

The most common grounds for the third-party observations and invalidation requests include lack of novelty or inventive step, clarity issues, insufficient disclosure and the claim not being supported by the description.

O: WHAT ARE THE PROCESSES FOR RE-EXAMINATION OF A PATENT?

After the applicant receives a decision of rejection from the examiner, he or she can file a request for re-examination to Department of Patent Re-examination and Invalidation within three months of the receipt of the decision. The request for re-examination will first be sent to the former examiner to see whether he or she changes his or her decision in view of the arguments or amendment presented. If the former examiner changes his or her decision, the re-examination process will end and the application will be continuously examined by the former examiner. If the former examiner insists on his or her prior decision, the request for re-examination will be examined by a panel consisting of three experienced examiners different from the former examiner. The panel, if it is not convinced by the applicant, will issue a notification of re-examination and give the applicant further chances to present arguments or amendments. Usually, after one or two notifications, a decision of re-examination, which may revoke the decision of rejection or uphold the decision of rejection, will be issued.

Q: WHAT IS THE PROCESS FOR INVALIDATION OR REVOCATION OF A PATENT? WHO HAS STANDING TO REQUEST INVALIDATION? HOW LONG DO INTER PARTES INVALIDATION CASES TAKE?

After the granting date of a patent, anyone holding that the patent does not comply with the provisions of the Chinese Patent Law can file a request for invalidation before the CNIPA. The party intending to file a request for invalidation could decide, as required, whether to file the request in its true name or through a straw man. Examination of a request for invalidation comprises formal examination and collegiate examination. The formal examination is to examine the object of the request, the eligibility of the petitioner, and the scope, causes and evidence supporting the request, among other things. After passing through the formal examination, the Department of Re-examination and Invalidation will transfer documents to the parties and assign a time limit (usually one month) for a response. The petitioner could submit supplementary evidence within one month of the date of filing the request, and the patentee could file an answer or evidence within the assigned time limit. A panel will be set up to examine the scope, causes and evidence provided by the parties, which is called the collegiate examination. The panel can decide whether the collegiate examination will be conducted in written form or via oral proceedings. The whole process usually lasts six to nine months.

Q: HOW CAN OPPOSITION, RE-EXAMINATION OR INVALIDATION DECISIONS BE APPEALED?

As for the pre-grant opposition (called third-party observations in China), there is no ability to appeal.

As for the re-examination and invalidation decisions, a party unsatisfied with the decision could file a lawsuit before the Beijing IP Court within three months of receipt of the decision. The Beijing IP Court would have a trial through one or several rounds of court hearings and then make a judgment of first instance. Any party unsatisfied with the judgment could file an appeal before the Intellectual Property Tribunal of the Supreme Court. The judgment made by the Supreme Court would be the final judgement.

Q: IS ADMINISTRATIVE ENFORCEMENT OF PATENTS POSSIBLE?

A granted patent can be enforced via two approaches: administrative enforcement and judicial enforcement. Administrative enforcement means that the patentee or the interested party could file an administrative complaint with the administrative authority, such as the local IP office or State Administration of Market Regulation, to require the infringer to stop

the infringement. The administrative authority would conduct an examination and determine whether the infringing product falls into the scope of protection of the patent-in-suit. If yes, the authority will order the infringer to stop the infringement. The authority has no right to require the infringer to compensate for damage caused by its infringement, which is a defect of the administrative enforcement. Any party unsatisfied with the decision made by the administrative authority can file a lawsuit before the local court.

O: DOES YOUR JURISDICTION GRANT PATENT-TERM EXTENSIONS?

If a patent for invention (granted after 1 June 2021) is granted after three years from the date of filing a substantive examination and after four years from the date of filing a patent application, the CNIPA, on request of the patentee, could grant a patent-term extension to compensate the unreasonable delay during the process, unless the delay was caused by the applicant. The request for patent-term extension should be filed within three months since announcement date of the patent.

Starting from 1 June 2021, for the patent of new approved drug to be launched in the Chinese market, a patent-term extension is also available, which must not be more than five years, and the entire term of the patent after the approval of the drug must not be over 14 years. The patent-term extension request for a drug-related patent should be filed with the CNIPA within three months of the approval date of the drug.

Q: IS THERE ANYTHING ELSE ABOUT PATENT ADMINISTRATIVE PROCEDURES THAT PATENT OWNERS AND CHALLENGERS SHOULD KNOW?

In the request for invalidation, the patentee is allowed to make amendment to the claims. However, the amendment shall be limited to deletion of a claim, combination of claims or technical features recited in the claims, and deletion of a technical solution. Before the CNIPA makes a decision on the request for invalidation, the patentee may either delete a claim or a technical solution contained in a claim. The patentee may combine claims and technical features only in response to the request for invalidation, or to the causes for invalidation or evidence added by the petitioner, or to causes for invalidation or evidence not mentioned by the petitioner but introduced by the Department of Re-examination and Invalidation.

As for administrative litigation before the Beijing IP Court, procedural documents such as power of attorney, identity certificates of legal representatives, and the company register or identifications must be notarised by local notary and legalised by the Chinese embassy or consulate if the plaintiff is a foreign entity or individual. Considering the time required for notarisation and legalisation, the Beijing IP Court provides a three-month extension of the time limit for filing the litigation as provided by the Chinese Patent Law.

Please note that these questions serve as a framework for each article. Authors may give greater emphasis to those questions that address key issues within the jurisdiction, at their discretion. Specific focus should be made to the most recent developments in your market.





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Germany: patent prosecution

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HOW DO YOU GET A PATENT IN YOUR JURISDICTION?

Q: WHAT TYPES OF PATENT ARE GRANTED IN YOUR JURISDICTION, AND WHAT RIGHTS DO THEY CONFER ON OWNERS?

Patents are granted for technical inventions. Technically, inventions are usually in the field of engineering, chemistry, pharmaceuticals and physics. In contrast to other jurisdictions (eg, the United States), non-technical inventions (eg, business methods) cannot be patented in Germany. Besides patents, protection for a technical invention can be obtained through a utility model. However, methods are excluded from protection by utility models. The main rights conferred by patents (and utility models) include claims to request an infringing party cease and desist infringing activity and claims for damages. However, products and processes protected by a patent may be used for private use or research.

Q: WHAT INVENTIONS ARE ELIGIBLE FOR PATENT PROTECTION IN YOUR JURISDICTION?

All technical inventions are eligible for patent protection. Non-technical subject matter is excluded. Besides technicity, inventions must fulfil the requirements of being novel, inventive and industrially applicable.

Q: ARE THERE ANY SPECIFIC EXEMPTIONS TO PATENT ELIGIBILITY?

Discoveries, scientific theories, mathematical methods, aesthetic creations, schemes, rules and methods for performing mental acts, playing games or doing business, computer programs and presentations of information are excluded from patentability. This exclusion is relevant only if the subject matter or activity relates to such subject matter or activity as such. If the subject matter or activity comprises a solution to a technical problem, then it is not considered subject matter or activity as such. Therefore, for example, computer software can be protected by means of a patent if the software solves a technical problem.

Further, the human body at the various stages of its formation and development (including germ cells) and the mere discovery of one of its components (including the sequence or partial sequence of a gene) are not patentable inventions. However, an isolated component of the human body or a component otherwise obtained by a technical process (including the sequence or partial sequence of a gene) may be patentable, even if the structure of such component is identical to the structure of a natural component.

The following are not patentable:

- · mere discoveries;
- · scientific theories and mathematical methods;
- · aesthetic creations of form;
- plans, rules and procedures for mental activities, games or business activities;
- · computer programs as such;
- · the reproduction of information as such;
- inventions, the commercial exploitation of which is contrary to public order or morality (eg, torture devices, letter bombs, apparatus for prohibited games of chance or for the production of clearly unhealthy or dangerous food or drink);

- plant varieties and animal breeds;
- the human body in the individual phases of its formation and development, as well as the mere discovery of one of its components, including the sequence or partial sequence of a gene;
- methods for cloning human beings;
- procedures for modifying the genetic identity of the germ line of human beings;
- the use of human embryos for industrial or commercial purposes;
- processes for modifying the genetic identity of animals, that involve suffering of these animals without these procedures being of significant medical benefit; and
- procedures for the surgical or therapeutic treatment of the human or animal body and diagnostic procedures.

Q: ARE THERE TECHNOLOGY-SPECIFIC ELIGIBILITY ISSUES THAT APPLICANTS MUST NAVIGATE (EG, IN SOFTWARE, BUSINESS METHODS, AI, MEDICAL DIAGNOSTICS, PHARMACEUTICALS, MEDICAL PROCEDURES, ETC)?

Software, business methods and AI can be patented only if they contribute to a technical solution. Methods for medical treatments and diagnostics are excluded from patentability. However, pharmaceuticals can be protected. There is even patent protection for a second indication of pharmaceuticals (second medical use claims).

If the subject matter of the invention is a sequence or partial sequence of a gene whose structure is identical to the structure of a natural sequence or partial sequence of a human gene, its use, for which the industrial applicability is specifically described, will be included in the patent claim.

O: WHAT ARE THE TIME AND COSTS INVOLVED IN SECURING A GRANTED PATENT? IS EXPEDITED EXAMINATION AVAILABLE? ARE REDUCED FEES AVAILABLE FOR CERTAIN **APPLICANTS?**

Examination of the patent application can be started by the applicant at any time in the first seven years of the patent application by filing a request for substantive examination. Therefore, the applicant can control whether the application will be granted soon after filing or whether the examination will be deferred. Late examination will result in the late grant of the patent. When deferring examination, the costs can be postponed correspondingly. Costs until grant are, on average, between €5,000 and €12,000. An expedited examination is available without an official fee. There is no fee reduction for certain applicants.

Q: WHAT ARE ANY SPECIFIC REQUIREMENTS THAT A PATENT SPECIFICATION MUST MEET IN YOUR JURISDICTION?

The patent application can be filed in any language, but a German translation must be filed afterwards. Depending on the filing language and priority claims, the deadline for filing the translation can vary. There is no fee for the late filing of a translation.

There are no further specific requirements.

Q: WHAT RULES GOVERN THE FILING OF PROVISIONAL APPLICATIONS, CONTINUATIONS OR CONTINUATIONS-IN-PART, DIVISIONALS OR ANY OTHER SPECIAL **TYPE OF APPLICATION?**

Divisional applications can be filed as long as the patent application is pending. There is no provisional application, continuation or continuation in part. However, it is possible to file a patent application without paying a filing fee to receive a filing date that can be used as a priority date for further patent applications. This is a cheap and efficient way for securing an early priority date.

Q: WHAT DO APPLICANTS NEED TO KNOW ABOUT OFFICE ACTIONS AND PATENT EXAMINER INTERVIEWS?

For each patent application there is the possibility to request an examiner interview. If the applicant does not agree with the examiner during the written procedure on the grant of the patent application, the examiner will schedule the interview. The interview usually takes part in a personal meeting with the examiner at the German Patent and Trademark Office (GPTO). Applicants can join the interview.

Q: ARE THERE ANY RECENT EXAMINATION TRENDS THAT PATENT APPLICANTS NEED TO BE AWARE OF?

Not applicable.

Q: IS THERE ANYTHING ELSE ABOUT THE PATENT FILING PROCESS THAT APPLICANTS SHOULD KNOW?

For entering the German phase based on an international (Patent Cooperation Treaty) application, a deadline of 30 months applies, within which a German translation of the international application must be filed.

In Germany a law protecting employees' inventions exists. Inventions made by employees in Germany may oblige the employer to pay the employee inventor compensation when IP rights resulting from a notice of an invention by that employee are used by the employer or even when they are kept confidential. The amount of the compensation is calculated according to official regulations based on the principle of royalties.

Q: IS UTILITY MODEL OR PETTY PATENT PROTECTION OR AN EQUIVALENT AVAILABLE IN YOUR JURISDICTION? IF SO, HOW DOES THE SYSTEM WORK AND UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE USING IT?

A utility model can be filed with the GPTO. Only device claims are permitted in utility models. Utility models are not examined with regard to the requirements for protectability (eg, novelty and inventiveness) but only for formal requirements. However, a search for prior art can be requested. The maximum duration of a utility model is 10 years, compared to 20 years for patents. There is a six-month grace period before the priority date or the filing date of the utility model in which the inventor or their legal successor can disclose the invention without harming the utility model. Therefore, it is advisable to file a utility model if there is a prior publication. A utility model application can be branched off from a pending German patent application, European patent application or Patent Cooperation Treaty application. The branched-off utility model application receives the same filing date as the corresponding patent application. When branching off, the utility model usually gets registered and becomes valid within a few weeks. Therefore, by branching off a utility model a valid right can be easily and quickly obtained and used against potential competitors. Since the utility model does not get examined, there is a certain risk about its value. However, when branching off from a pending patent application, search results for the patent application may be received and can be used to tailor the claims of the utility model so that it is novel



and inventive and still encompasses the competitor's embodiment, as long as the claims are within the scope of disclosure of the patent application.

Q: UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE A NATIONAL PROSECUTION TO SECURE PROTECTION IN YOUR JURISDICTION RATHER THAN GOING DOWN THE EPO ROUTE?

National German prosecution is advisable if the product's key market is in Germany or the majority of competitors are located in Germany. A German patent application is significantly cheaper than taking the EPO route.

WHAT ARE THE MAJOR ADMINISTRATIVE PROCEDURES IN YOUR JURISDICTION?

Q: HOW CAN APPLICANTS APPEAL PATENT OFFICE DECISION?

Patent office decisions can be appealed by filing an appeal within one month of receipt of the appealable decision. The appeal must be filed at the GPTO. Although there is no official deadline for filing the grounds of appeal, it is recommended they be filed shortly after or ideally when filing the appeal itself. Depending on the nature of the proceedings, the fees for filing an appeal are between €200 and €500.

Q: ARE OPPOSITIONS AVAILABLE PRE-GRANT OR POST-GRANT? WHAT RULES GOVERN STANDING TO OPPOSE A PATENT AND THE OPPOSITION PROCESS?

Oppositions are available post-grant. The deadline for filing an opposition is nine months after the publication of the grant together with an opposition fee of €200. A patent can be opposed based on a lack of the requirements that are needed for patentability (eg, technicity, novelty, inventiveness and sufficient disclosure).

Q: WHAT ARE THE PROCESSES FOR RE-EXAMINATION OF A PATENT?

There is no re-examination process, but a nullity suit against granted patents is available. This procedure is usually used in parallel with patent litigation procedures before the civil courts. A nullity action should be filed at the Federal Court of Patents. Appeal to the Federal High Court of Justice is possible. A nullity action is even available after the patent has ended if there is a legal interest.

Q: WHAT IS THE PROCESS FOR INVALIDATION OR REVOCATION OF A PATENT? WHO HAS STANDING TO REQUEST INVALIDATION? HOW LONG DO INTER PARTES INVALIDATION CASES TAKE?

To invalidate or revocate a patent, an opposition or a nullity suit can be filed. While the opposition must be filed within nine months of the publication of the grant of the patent at the GPTO, the nullity suit must be filed with the Federal Patent Court. Both can be filed by any party. The duration of an opposition proceeding is usually between three and five years, while a nullity suit usually takes about four to six years. Even after a patent has ended due to its 20-year time limit, a nullity suit can still be filed if a party is accused of patent infringement in the past.

Q: HOW CAN OPPOSITION, RE-EXAMINATION OR INVALIDATION DECISIONS BE APPEALED?

Decisions by the opposition department can be appealed by filing an appeal to be processed before the Federal Patent Court. Under certain circumstances appeal against Federal Patent Court decisions can be taken to the Federal High Court of Justice.

Q: IS ADMINISTRATIVE ENFORCEMENT OF PATENTS POSSIBLE?

No, this is not applicable to Germany.

Q: DOES YOUR JURISDICTION GRANT PATENT-TERM EXTENSIONS?

Yes, if the patent was granted for an active ingredient, substance or a combination of active ingredients or substances, or a medical or plant protection product, then a patent-term extension can be granted. Under certain circumstances, it is possible to have the term of protection extended by a supplementary protection certificate by up to five years and for a further period of up to six months if studies recognise medical products for paediatric use.

Q: IS THERE ANYTHING ELSE ABOUT PATENT ADMINISTRATIVE PROCEDURES THAT PATENT OWNERS AND CHALLENGERS SHOULD KNOW?

Unlike other jurisdictions, Germany generally permits the late filing of new requests or new material that will be considered by the decisive body. It is possible in such complex procedures as patent prosecution or opposition procedures to enter with new arguments at a late stage.



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India: patent prosecution

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HOW DO YOU GET A PATENT IN YOUR JURISDICTION?

Q: WHAT TYPES OF PATENTS ARE GRANTED IN YOUR JURISDICTION, AND WHAT RIGHTS DO THEY CONFER ON OWNERS?

India has a robust patent system that incentivises innovators and takes care of public and national interests. India grants patents for inventions relating to products and processes. For products protected by a patent, the patentee has the exclusive right to prevent third parties from making, using, offering for sale, selling or importing for those purposes that product in India. For a process protected by a patent, the patentee has the exclusive right to prevent third parties from using that process, and from using, offering for sale, selling or importing for those purposes the product obtained directly by that process in India. Apart from that, India has enacted different statutes for the protection of design, layout design and plant varieties, and therefore, these are not covered under the Patent Law. However, India does not have provisions for utility models (also known as petty patents).

Q: WHAT INVENTIONS ARE ELIGIBLE FOR PATENT PROTECTION IN YOUR JURISDICTION?

Patents are granted for inventions across all areas of science and technology, except those relating to non-patentable subject matters in India. Under the Indian Patent Law, an 'invention' means a new product or process involving an inventive step and capable of industrial application. A new invention is any invention or technology that has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of a patent application.

The inventive step is a feature of an invention that requires having technical knowledge to complete as opposed to basic knowledge or having economic significance, or both, and that feature makes the invention not obvious to a person skilled in the art.

'Capability for industrial application' means that the invention is capable of being made or used in industry.

O: ARE THERE ANY SPECIFIC EXEMPTIONS TO PATENT ELIGIBILITY?

The following are not patentable under Indian Patent Law:

- · inventions that go against natural laws;
- anything contrary to public order or morality or that is harmful;
- discoveries or theories;
- discoveries of new forms, properties or uses of a known substance;
- · uses of a known process or machine;
- · substances obtained by an admixture;
- arrangements of known devices;
- · methods of agriculture or horticulture;
- · methods of treatment;
- · plants and animals;
- mathematical methods;

- · business methods;
- · computer programs;
- · algorithms;
- · aesthetic creations;
- schemes or rules;
- · methods of performing a mental act;
- · methods of playing a game;
- presentations of information;
- · topographies of integrated circuits;
- · traditional knowledge; and
- · inventions relating to atomic energy.

Q: ARE THERE TECHNOLOGY-SPECIFIC ELIGIBILITY ISSUES THAT APPLICANTS MUST NAVIGATE (E.G., IN SOFTWARE, BUSINESS METHODS, AI, MEDICAL DIAGNOSTICS, PHARMACEUTICALS OR MEDICAL PROCEDURES)?

The Indian Patent Office (IPO) generally objects to the subject matter eligibility of computer-related inventions (CRIs) under Section 3(k) of the Patents Act 1970, which bars the patentability of inventions directed towards "a mathematical or business method or a computer program per se or algorithm". The IPO has also issued separate guidelines for the examination of CRIs, which emphasise that while examining CRIs, examiners should focus on ascertaining the substance of the claims as a whole and not in the form of the claims. If, in substance, the invention is technical and the invention achieves a 'technical effect', then the invention does not fall under excluded subject matter. India's stand on CRIs is like the European and UK position.

In the field of pharmaceutical drugs, to prevent patent evergreening, Section 3(d) of the Patents Act 1970 excludes, inter alia, inventions that relate to "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance" from patentability. Here, "efficacy" means therapeutic efficacy according to the case law.

Further, any invention which relates to a process for medical treatment of human beings or animals is excluded from patentable subject matter under Section 3(i) of the Patents Act 1970. While methods of treatment are non-patentable subject matter, medical devices do not fall under this category.

O: WHAT ARE THE TIME AND COSTS INVOLVED IN SECURING A GRANTED PATENT? IS AN EXPEDITED EXAMINATION AVAILABLE? ARE REDUCED FEES AVAILABLE FOR CERTAIN APPLICANTS?

With continuous effort, the long backlog of patent applications pending examination has been largely cleared. Currently, it takes about three years for a patent to be granted in India provided the applicant completes all actions in a timely manner. Expedited examination is also available, but only to a select category of applicants upon payment of an additional fee. Under expedited examination, a patent can be granted within a year.

For official fee calculation purposes, applicants are either: (1) natural persons, start-ups, small entities or educational institutions; or (2) all others that do not fit into the first category (eg, large entities). The applicants that fall under the first category get an approximate 80% discount on the official fee. Foreign applicants can also avail themselves of the benefit of the discounted fee provided they belong in the first category of applicants. There is a surcharge of 10% on the official fee for all physical filings to promote the e-filing of documents.

The overall cost of obtaining a patent in India is less than in the United States and Europe. As English language filings are acceptable, there are no additional costs for translation at the time of filing or prosecution. The end-to-end cost of obtaining protection in India is generally between \$3000 to \$4000.

Q: WHAT ARE ANY SPECIFIC REQUIREMENTS THAT A PATENT SPECIFICATION MUST MEET IN YOUR JURISDICTION?

To get a patent in India, every complete specification must:

- fully and in detail describe the invention, and its operation or use and how to use it;
 and
- disclose the best way to use the invention that is known to the applicant and for which they are entitled to claim protection.

Further, the claim must relate to a single invention, or to a group of inventions linked by a single inventive concept; must be clear and succinct; and must be fairly based on the matter disclosed in the specification.

Q: WHAT RULES GOVERN THE FILING OF PROVISIONAL APPLICATIONS, CONTINUATIONS OR CONTINUATIONS-IN-PART, DIVISIONALS, OR ANY OTHER SPECIAL TYPE OF APPLICATION?

The following five types of patent applications can be filed in India:

- ordinary applications;
- · conventional applications;
- Patent Cooperation Treaty national phase applications;
- · divisional applications; and
- patent of additions.

Only an ordinary application can be filed with a provisional specification and all other types of applications can be filed with a complete specification only.

A divisional application can be filed by the applicant voluntarily or to remedy the objection on the unity of the invention at any time before the patent is granted. Divisional applications cannot contain claims that were not claimed in the parent application. This means that the claims of the divisional application must be derived from the claims of the parent application only.

The patent of addition, which is akin to a continuation-in-part application, can be filed regarding any improvement or modification of an invention described or disclosed in the complete specification filed for the main invention. A patent of addition cannot be granted for the main invention before a patent is.

There is no provision under Indian Patent Law for a continuation application to claim any unclaimed subject matter. In fact, what is not claimed is considered disclaimed under the doctrine of disclaimer.

Q: WHAT DO APPLICANTS NEED TO KNOW ABOUT OFFICE ACTIONS AND PATENT EXAMINER INTERVIEWS?

The application is examined by the IPO after a request for examination or expedited examination is filed. Once the application is examined, a first examination report (FER) is issued by the IPO listing various objections. The applicant is required to file a response to the FER within six months, which can be further extended once by a maximum of three months provided that a request for extension is filed before the expiry of the initial six-month period. Thereafter, the IPO examines the response and proceeds to grant a patent if all the objections have been addressed and there are no new objections based on the response.

Alternatively, if some objections have not been addressed or the IPO raises new objections based on the response, a hearing notice is issued providing the applicant at least 10 days' notice in advance of the hearing. During the hearing, objections raised in the hearing notice are discussed, and the applicant or applicant's agent presents their case before the Controller in charge of the application. After the hearing, the applicant is required to file written submissions within 15 days of the date of the hearing. Thereafter, the IPO examines the submissions filed by the applicant and proceeds to grant a patent if all the objections raised in the hearing notice have been addressed by the applicant. If the IPO does not agree with the submissions, the application is refused.

Q: ARE THERE ANY RECENT EXAMINATION TRENDS THAT PATENT APPLICANTS NEED TO BE AWARE OF?

REDUCED BACKLOG

The completion time of a patent application in India now is substantially less than in recent years. Thanks to extensive recruitment at the IPO and other procedural reforms, the average time to complete an application has been reduced from seven to eight years (the average prosecution time a decade ago) to two to three years.

DIVISIONAL APPLICATIONS

India does not have provisions for continuation applications, and a divisional application filed for merely prolonging the patent prosecution is not maintainable. Divisional application claims need to be directed towards a distinct invention, which is different to the process for parent application claims. As per a recent judicial precedent, Boehringer v Controller of Patents, divisional application claims need to be divided from parent application claims. Therefore, a divisional application claiming any unclaimed subject matter from the parent application is likely not maintainable.

AMENDMENTS

Provisions relating to claim amendments require that amended claims not go beyond the scope of the original claims and be supported by the specification. That is why replacement or addition of claims is generally not permissible. According to another recent <u>judicial precedent</u>, *Nippon v Controller of Patents*, amendments to patent specifications or claims before the patent is granted must be construed more liberally than narrowly. Nothing new

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can be inserted, but if an amendment restricts claims to disclosures already made, the amendment ought not to be rejected, especially before the grant of a patent.

Q: IS THERE ANYTHING ELSE ABOUT THE PATENT FILING PROCESS THAT APPLICANTS SHOULD KNOW?

India allows for the deletion of claims while filing national applications in India. Accordingly, applicants can delete claims to delete non-patentable claims and save on excess claim fees. Further, the applicants can also file certified copies of priority documents and verified English translations thereof (wherever applicable) at the time of filing the application. This allows the applicants to avoid any late fees that they might have to pay at a later stage during the prosecution of the application.

Q: IS UTILITY MODEL OR PETTY PATENT PROTECTION OR AN EQUIVALENT AVAILABLE IN YOUR JURISDICTION? IF SO, HOW DOES THE SYSTEM WORK AND UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE USING IT?

India does not have any provisions for utility models or petty patents.

Q: FOR EUROPEAN FIRMS: UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE A NATIONAL PROSECUTION TO SECURE PROTECTION IN YOUR JURISDICTION RATHER THAN GOING DOWN THE EPO ROUTE?

Not applicable.

WHAT ARE THE MAJOR ADMINISTRATIVE PROCEDURES IN YOUR JURISDICTION?

O: HOW CAN APPLICANTS APPEAL PATENT OFFICE DECISION?

Once an application is refused by the IPO, an applicant has two options: review the refusal order or appeal against the refusal order. A review petition can be filed at the IPO within one month of the date of the refusal order. The review petition is placed before the same Controller of the IPO who refused the application. Accordingly, the review petition should be filed only in cases where there is an apparent error in the refusal order or the Controller is willing to consider the review petition on merits, or both. On the other hand, an appeal can be filed before the high court within three months of the date of the refusal order. If the appeal is allowed by the relevant high court, the refusal order is set aside and the matter is sent back to the IPO for re-examination. The appeal may be costly, but it is a more effective option to obtain a favourable decision on substantial grounds.

Q: ARE OPPOSITIONS AVAILABLE PRE-GRANT OR POST-GRANT? WHAT RULES GOVERN STANDING TO OPPOSE A PATENT AND THE OPPOSITION PROCESS?

Pre-grant opposition can be filed by any person after the publication of an application and before the patent is granted on any of the grounds provided under the of the Patents Act 1970. Given recent court orders, anonymous oppositions ought to be discouraged by the IPO. In practice, pre-grant opposition can be used to delay the granting of a pending patent. Sometimes, straw men have been used to file a series of pre-grant oppositions to delay the grant. A pre-grant opposition is considered only when a request for examination has been filed. After consideration of the maintainability of pre-grant opposition, the IPO issues a notice of opposition to the applicant. The applicant is required to file a reply statement within three months of the date of such notice. Thereafter, after hearing both parties, the Controller issues an order either granting a patent or refusing the application.

A post-grant opposition can only be filed by an interested person within one year of the date of publication of the grant of a patent. An interested person includes a person engaged in, or promoting, research in the same field as that to which the invention relates. The patentee is required to file a statement of reply within two months of the date of receipt of the opponent's written statement in support of the opposition. The opponent can file a reply to the statement of reply of the patentee within one month of the date of receipt of the patentee's statement of reply. The Controller then appoints an opposition board that examines the notice of opposition, along with documents filed by both parties, and submits a report with reasons on each ground taken in the notice of opposition with its joint recommendation within three months of the date on which the documents were forwarded to them. Thereafter, the Controller, after hearing both parties, either rejects the opposition or revokes the patent.

Q: WHAT ARE THE PROCESSES FOR RE-EXAMINATION OF A PATENT?

India does not have any provision for the re-examination of a patent. However, provisions for pre-grant opposition proceedings any time before the grant, post-grant opposition proceedings up to one year after the grant and revocation proceedings any time after the grant have been provided under the of the Patents Act 1970 for accommodating third-party representations at various stages of patent life cycle and in different forums.

Q: WHAT IS THE PROCESS FOR INVALIDATION OR REVOCATION OF A PATENT? WHO HAS STANDING TO REQUEST INVALIDATION? HOW LONG DO INTER PARTES INVALIDATION CASES TAKE?

A petition for revocation of a patent can be filed by an interested person or by the central government before a high court with jurisdiction. The petition for revocation of a patent also lies with the high court if a counterclaim regarding the validity of a patent is made by the defendant in a suit for infringement of that patent. The procedure to be followed for disposal of such cases is provided under the Commercial Courts Act 2015 as intellectual property-related cases are considered commercial matters, and therefore, speedy disposal of such matters happens as mandated by the Commercial Courts Act 2015.

A patent can also be revoked under the following conditions:

- revocation of a patent owing to the non-workability under section 85 of the of the Patents Act 1970;
- revocation of a patent in public interest by the Central Government under section 66 of the Patents Act 1970; and
- in cases relating to atomic energy on the directions of the Central Government under section 65 of the Patents Act 1970.

The erstwhile Intellectual Property Appellate Board (IPAB) was recently abolished, which used to take care of the revocation matters, and the jurisdiction of these cases has been transferred to the high courts. Accordingly, it is difficult to anticipate how long it will take the high courts to dispose of revocation matters without the availability of sufficient data to date.

The Delhi High Court created the IP Division for handling all intellectual property rights (IPR) matters, including those that are to be transferred from the IPAB. To date, three single-judge benches of the Delhi High Court are acting as the IP Division to exclusively hear all IPR-related matters, including the appeals arising out of the decisions of the Controller of

Patents, Registrar of Trademarks, Controller of Designs, Registrar of Copyright, Registrar of Geographical Indications and the Plant Variety Authority.

Other high courts may also follow the initiative of the Delhi High Court and may soon set up IP divisions in those courts. The High Court of Delhi notified the Intellectual Property Division Rules and the Rules Governing Patent Suits early in 2022.

Q: HOW CAN OPPOSITION, RE-EXAMINATION OR INVALIDATION DECISIONS BE APPEALED?

The Patents Act 1970 provides that an order from the Controller in respect of a post-grant opposition can be appealed before the High Court within three months of the date of the order. The Act does not expressly provide that a pre-grant opposition order is appealable. However, in practice, the pre-grant opposition order can be appealed considering this as an order under Section 15 of the Patents Act 1970, which is a usual order of the Controller either allowing or refusing an application, and the Act expressly provides that such orders can be appealed. Further, the writ jurisdiction of the high courts can also be availed against such orders rejecting the application. The Patents Act 1970 also does not expressly provide that a revocation order can be appealed. However, in practice, an order of the high court in a revocation petition can be appealed by the aggrieved party under the letters patent appeal before a division bench of the same high court.

Q: IS ADMINISTRATIVE ENFORCEMENT OF PATENTS POSSIBLE?

India notified the Intellectual Property Rights (Imported Goods) Enforcement Rules 2007 to bring the country more in line with the border measures available under the Agreement on Trade-Related Aspects of Intellectual Property Rights. These Rules allowed customs officers of the customs department to enforce IPRs over imported products. These Rules were also applicable to patents when they were notified. However, in 2018 revised rules were notified, and enforcement of patents was excluded from the rules. Accordingly, presently, patents can only be enforced in the court orders in a suit for infringement before a high court.

Q: DOES YOUR JURISDICTION GRANT PATENT-TERM EXTENSIONS?

India does not have any provisions for the extension of the term of a patent beyond 20 years from the date of filing or priority, whichever is earlier.

Q: IS THERE ANYTHING ELSE ABOUT PATENT ADMINISTRATIVE PROCEDURES THAT PATENT OWNERS AND CHALLENGERS SHOULD KNOW?

Under Section 8(1) of the Act, an applicant is required to furnish the status or details of corresponding foreign applications within six months of the date of filing the application in India or the date of filing the corresponding foreign application, whichever is later. The applicants should diligently file the status of the applications at regular intervals because non-filing of the information is also a ground for opposition or revocation. Under Section 8(2) of the Act, Applicants are required to submit, only when asked by the IPO, allowed claims and office actions from other jurisdictions with English translations if required. Copies of prior art references cited in other jurisdictions are not required.

Further, patentees and licensees are required to submit annual working statements indicating whether the patented invention has been worked or not. If the patent has been worked, the patentee or licensee is required to provide an approximate value accrued by them as a result of sales of the patented product or the product implementing the patented

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technology in India. Non-submission of the working statement attracts penalties. The format of the working statement has been simplified and is still under discussion for further improvements.



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Israel: patent prosecution

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HOW DO YOU GET A PATENT IN YOUR JURISDICTION?

Q: WHAT TYPES OF PATENT ARE GRANTED IN YOUR JURISDICTION, AND WHAT RIGHTS DO THEY CONFER ON OWNERS?

Patents are governed by the Patents Law 5727-1976 (the Patents Law), as well as by various regulations relating to patents.

In Israel, it is only possible to obtain utility patents.

Q: WHAT INVENTIONS ARE ELIGIBLE FOR PATENT PROTECTION IN YOUR JURISDICTION?

The Patents Law provides that for an invention to be patentable – be it a product or a process, in any technology field – it must be novel and useful, have industrial application and involve an inventive step.

Q: ARE THERE ANY SPECIFIC EXEMPTIONS TO PATENT ELIGIBILITY?

The following are excluded by the Patents Law:

- procedures for therapeutic treatments for the human body; and
- new varieties of plants or animals, except microbiological organisms not derived from nature.

Q: ARE THERE TECHNOLOGY-SPECIFIC ELIGIBILITY ISSUES THAT APPLICANTS MUST NAVIGATE (EG, IN SOFTWARE, BUSINESS METHODS, AI, MEDICAL DIAGNOSTICS, PHARMACEUTICALS, MEDICAL PROCEDURES, ETC)?

The Patents Law excludes from patent eligibility procedures for therapeutic treatments for the human body and new varieties of plants and animals, except microbiological organisms not derived from nature.

In addition, discoveries, scientific theories, mathematical formulas, rules for playing games and mental acts, as such, are considered abstract ideas or processes devoid of technical character. Yet, a technological character may be established by combining the aforementioned ideas and processes with additional technological means, resulting in products and processes in technological fields that are eligible for patent protection.

Q: WHAT ARE THE TIME AND COSTS INVOLVED IN SECURING A GRANTED PATENT?

According to the Israeli Patent Office's (IPO) 2021 annual report, the average time from filing an application to the end of examination is 41.8 months. There is a difference between different technological fields, with the examination of applications in the field of biotechnology taking the longest (on average, 20.3 months from the issue of the first official notification) and applications in the fields of mechanics, electronics and physics taking the shortest (on average, 11.8 months from the issue of the first official notification).

According to the IPO's 2022 fee schedule, the following costs are involved in securing a granted patent:

- standard filing fee: NIS2,077;
- extra claim fee: NIS533 (for each additional claim over 50);

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extra page fee: NIS260 (for each additional page over 50, not including sequence listing);

- · extension fee per month: NIS208; and
- · acceptance and publication fee: NIS727.

Q: IS EXPEDITED EXAMINATION AVAILABLE?

Expedited examination is available in Israel. There are five different available routes:

- acceleration under Section 19(a) of the Patents Law;
- · patent prosecution highway;
- green technology inventions;
- · modified examination; and
- early response to the combined international search report and written opinion.

ACCELERATION UNDER SECTION 19(A)

A petition for accelerated examination may be filed at the IPO in accordance with Section 19(a) of the Patents Law based on the following:

- · likelihood of infringement;
- · advanced age or applicant's medical condition;
- · public interest; and
- · unreasonably long delay in initiating examination by the IPO.

If the registrar is satisfied that the petition is well grounded, the examination of the application will commence as soon as possible after the filing of the petition, subject to the payment of the prescribed fee.

GLOBAL PATENT PROSECUTION HIGHWAY

A request for an accelerated examination under the patent prosecution highway programme may be filed with the IPO before substantive examination commences.

GREEN TECHNOLOGY INVENTIONS

Applications that relate to green technologies can be given a preferential status. Therefore, if the invention contributes to the environment by, for example, preventing global warming or decreasing contamination of air or water, the applicant may apply for preferential status that will lead to a special, expedited examination route.

MODIFIED EXAMINATION

Modified examination under Section 17(c) of the Patents Law can be based on a corresponding patent that has been granted in one of the following jurisdictions:

- · Australia;
- · Austria;
- · Canada;

- · Denmark;
- · the European Patent Office;
- · Germany;
- Japan;
- Norway;
- · Russia:
- · Sweden:
- the United Kingdom; or
- · the United States.

EARLY RESPONSE TO THE INTERNATIONAL SEARCH REPORT OF WRITTEN OPINION

An applicant may accelerate examination by filing a response to the international search report, written opinion or international preliminary examination report, as long as it is done before the issuance of the standard official notification prior to examination.

O: ARE REDUCED FEES AVAILABLE FOR CERTAIN APPLICANTS?

A 40% small-entity discount on the official filing fee and on the acceptance fee are available to individuals and to companies and partnerships with a turnover of under NIS10 million in the preceding year.

The small-entity discount is not available for a national phase of a Patent Cooperation Treaty application or for patent applications filed under the Paris Convention.

O: WHAT ARE ANY SPECIFIC REQUIREMENTS THAT A PATENT SPECIFICATION MUST MEET IN YOUR JURISDICTION?

The patent specification should include:

- · a title by which the invention can be identified;
- a description of the manner in which the invention can be performed, including, when necessary for the understanding of the invention, drawings, examples and sequences; and
- a claim (or claims) that defines the invention in a clear and concise manner, provided that each claim is supported by (reasonably arises out of) the description.

When the invention includes biological material that is not available to the public or the invention involves the use of a biological material that has been deposited in a deposit institute, reference to the deposit details must be included.

Where amino acid or nucleic acid sequences are recited in the specification, a list of the sequences should be submitted in a computer-readable form (XML file).

Q: WHAT RULES GOVERN THE FILING OF PROVISIONAL APPLICATIONS, CONTINUATIONS OR CONTINUATIONS-IN-PART, DIVISIONALS OR ANY OTHER SPECIAL **TYPE OF APPLICATION?**

The Patents Law allows for the filing of a divisional patent application. As long as the application has not been accepted, the applicant is entitled to request that it be divided into one or more patent application. Similarly, if the application includes more than one invention, then the registrar may, as long as the application has not been accepted, direct the applicant to divide the application.

Divisional applications can be further divided out of a pending divisional application before the pending divisional application is accepted. The date of each divisional patent application should be the same as that of the application from which it was divided, and it will enjoy same priority claims.

Q: WHAT DO APPLICANTS NEED TO KNOW ABOUT OFFICE ACTIONS AND PATENT EXAMINER INTERVIEWS?

A response to an official notification should be filed within four months of the date of issue of the notification. An applicant is entitled to request up to a four-month extension for each round of examination. The extensions available for the entire process of examination are limited to 12 months.

It is possible to conduct an interview with the examiner. During the interview it is possible to discuss various aspects of the invention, defects and possible corrections to overcome any defects. Scheduling an interview is conducted directly with the examiner and should be accompanied by a written notification of the interview initiative, including details of the issues to be discussed. A request for an interview does not replace the duty to respond to a pending official notification.

Q: ARE THERE ANY RECENT EXAMINATION TRENDS THAT PATENT APPLICANTS NEED TO BE AWARE OF?

The IPO issued the <u>Patent Examination Working Guidelines</u>, including guidelines relating to the examination of antibodies, polymorphs, overlap and computer-related inventions.

ANTIBODIES (APPENDIX V)

Claims to antibodies should include, among other things, any one of the following:

- the amino acid sequence of the entire antibody or the DNA segment encoding the antibody;
- the amino acid sequence of the variable regions or the complementarity-determining regions, or the DNA segment encoding these regions;
- the deposition number of the cell producing the antibody; or
- the specific process for producing the antibody or reference to a standard process for producing the antibody, based on the antigen description.

A claim defining an antibody by its properties and not by its structure is considered a functional claim and would therefore be examined in accordance with Section 13(b) of the Patents Law.

POLYMORPHS (APPENDIX T)

The guidelines define, among other things, unity, novelty, inventive step and claims requirements.



With respect to the claims, it is important to highlight the requirement to characterise the polymorph by a specific number of peaks that precisely and unambiguously characterise the crystalline form (typically requiring 10 peaks having the highest intensity).

OVERLAP (APPENDIX E)

The guidelines relating to overlap concern two scenarios:

- overlap between an examined application and an additional patent or patent application with the same effective filing date (eg, parent and divisional); and
- overlap between an examined application and an additional patent or patent application with a different effective filing date.

In the first scenario, an overlap objection will be raised in the following cases:

- the applications claim the same aspect, wherein the scope of the claim in the examined application is identical (even if the claim is not literally identical) to the scope of the claim of the other application or patent; and
- the applications claim different aspects, wherein the claims provide an identical scope of protection (eg, product by-process claims and claims directed to the process) are considered to overlap.

In the second scenario, an overlap objection will be raised in the following cases:

- the applications claim the same aspect, wherein the scope of the claims in the
 examined application is identical to (literally or substantively), or includes or is
 included within, the scope of the claims of the earlier application; and
- the applications claim different aspects, but the claims essentially provide identical scope of protection (eg, product by-process claims and claims directed to the process) are considered to overlap.

A substantial overlap exists between claims of the examined application and the claims of the earlier application (whether the claims are directed to different aspects or to the same aspects), in the following cases:

- the difference between the claims does not constitute an essential element of the claimed invention; and
- the element that constitutes the difference was described or exemplified (even if it is not claimed) in the other application that has not yet been accepted.

COMPUTER-RELATED INVENTIONS (APPENDIX B)

Discovery, scientific theories, mathematical formulas, rules for playing games and mental acts, as such, as well as business methods *per se*, will be considered abstract ideas or processes that are devoid of technical character, irrespective of whether they are performed manually or by a computer.

When examining computer-implemented inventions, the working guidelines define that the invention should include a concrete technological character for the claimed product or process. A technological character may be formed by combining ideas or processes with additional technological means, and the invention, as a whole, should make a contribution

with a concrete expression in its technological field. This contribution of the invention, as a whole, will be examined with respect to the prior art.

Q: IS THERE ANYTHING ELSE ABOUT THE PATENT FILING PROCESS THAT APPLICANTS SHOULD KNOW?

Minimal requirements include the name of the applicant, specification (in Hebrew, Arabic or English, although if filed in Arabic, the IPO will obtain a translation) ending with at least one claim, address for service in Israel and payment of the prescribed fee.

Missing documents such as a power of attorney, a copy of the priority document and a translation, among other things, can be completed after filing.

PATENT OF ADDITION

If a patent owner is the owner of an invention that is an improvement or modification of an invention for which a patent has already been granted (ie, the main patent), then the owner may request that a patent for the second invention be granted to them as a patent of addition. The patent of addition need not involve an inventive step beyond the main patent. The patent of addition remains in effect for as long as the main patent is in effect. There is no need to pay any renewal fee with respect to the patent of addition, in addition to the fees paid for the main patent.

Q: IS UTILITY MODEL OR PETTY PATENT PROTECTION OR AN EQUIVALENT AVAILABLE IN YOUR JURISDICTION? IF SO, HOW DOES THE SYSTEM WORK AND UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE USING IT?

No, there is no utility model or petty patent protection in Israel.

WHAT ARE THE MAJOR ADMINISTRATIVE PROCEDURES IN YOUR JURISDICTION?

O: HOW CAN APPLICANTS APPEAL PATENT OFFICE DECISION?

An examiner's decision may be appealed to the registrar of patents, while a registrar's decision may be appealed to the court.

Q: ARE OPPOSITIONS AVAILABLE PRE-GRANT OR POST-GRANT?

Israel has a pre-grant opposition procedure.

Q: WHAT RULES GOVERN STANDING TO OPPOSE A PATENT AND THE OPPOSITION PROCESS?

The Patents Law provides that any person may, within three months of the date of the publication of acceptance of the application, oppose the grant of the patent by filing a written notice to the registrar of patents along with the prescribed fees.

The grounds for opposition can include any one of the following:

- the reason for which the registrar had the authority to refuse the patent application;
- the invention is not novel under Section 4(2) of the Patents Law; or
- the opponent, not the applicant, is the owner of the invention.

Q: WHAT ARE THE PROCESSES FOR RE-EXAMINATION OF A PATENT?

There is no formal procedure of re-examination after grant. Re-examination may occur if applicant requests amendment of the granted patent, or if an application for revocation of the patent is filed by a third party.

Q: WHAT IS THE PROCESS FOR INVALIDATION OR REVOCATION OF A PATENT? WHO HAS STANDING TO REQUEST INVALIDATION? HOW LONG DO INTER PARTES INVALIDATION CASES TAKE?

An applicant may request cancellation of a patent in its name. If granted, a third party may oppose the cancellation.

Any person other than the patentee may apply for revocation or cancellation of the patent.

Q: HOW CAN OPPOSITION, RE-EXAMINATION OR INVALIDATION DECISIONS BE APPEALED?

Decisions may be appealed to the court.

Q: IS ADMINISTRATIVE ENFORCEMENT OF PATENTS POSSIBLE?

The Patents Law deals with the state's right to exploit inventions.

Section 104 prescribes that the minister may permit the exploitation of an invention by government departments or by an enterprise or agency of the state, whether a patent for it has already been granted or has already been applied for, if he or she finds that that is necessary in the interests of national security or of the maintenance of essential supplies and services.

Further, Section 105 prescribes that the minister may, if he or she finds that it is necessary for the purposes enumerated in Section 104, grant a permit to a person who operates under contract with the state, to ensure or facilitate the implementation of that contract and for the requirements of the state only.

Q: DOES YOUR JURISDICTION GRANT PATENT TERM EXTENSIONS?

Yes. A patent for a pharmaceutical (substance) product or a medical device that requires marketing authorisation may be eligible for a patent term extension if it includes claims directed to any of the following:

- · a substance;
- · a process for manufacture of a substance;
- · use of a substance;
- a pharmaceutical preparation containing a substance;
- a process of manufacture of a pharmaceutical preparation containing a substance;
 or
- a medical device that requires marketing authorisation in Israel.

Q: IS THERE ANYTHING ELSE ABOUT PATENT ADMINISTRATIVE PROCEDURES THAT PATENT OWNERS AND CHALLENGERS SHOULD KNOW?

The IPO issued the Patent Examination Working Guidelines with the following appendices:

Appendix A: general guidelines for examining a patent application;

- · Appendix B: Section 3, patent-eligible inventions;
- Appendix C: Section 7, restrictions on the granting of patents;
- Appendix D: Section 8, unity of an invention (English version available);
- Appendix E: Sections 2, 9 and 19, overlap;
- Appendix F: Section 4, novelty (English version available);
- Appendix G: Section 5, inventive step;
- Appendix H: principles for patent classification;
- · Appendix I: guidelines for prior art search;
- · Appendix J: Section 10, priority claims;
- · Appendix K: Section 13, the claims;
- · Appendix L: Section 12, the description;
- Appendix M: Section 17(c), examination and acceptance based on a corresponding patent;
- · Appendix N: use of disclaimers in claims;
- Appendix T: examination guidelines for polymorphs and salts (English version available);
- · Appendix U: Section 23, specification amendments;
- · Appendix V: examination of applications on antibodies; and
- · interview with the examiner.



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Mexico: patent prosecution

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Q: WHAT TYPES OF PATENT ARE GRANTED IN YOUR JURISDICTION, AND WHAT RIGHTS DO THEY CONFER ON OWNERS?

There are patents and utility models.

Patents have a 20-year term while utility models have a 15-year term, both counted from the filing date of the application.

Patents protect claims related to:

- · products or process specially devised for their manufacture or use;
- processes, apparatus or means specially devised for their application; and
- certain products or processes specially devised for their manufacture, or apparatus or means specially devised for their application.

The exclusive right of exploitation of the patented invention confers the following prerogatives on its owner:

- Patented product: prevents third parties from manufacturing, using, selling, offering for sale or importing the product without the owner's consent.
- Patent process: prevents third parties from using that process and from using, selling, offering for sale or importing the product obtained directly by the process, without the owner's consent.

Q: WHAT INVENTIONS ARE ELIGIBLE FOR PATENT PROTECTION IN YOUR JURISDICTION?

Inventions in all fields of technology are patentable when having the following characteristics:

- new: not part of the state of the art;
- inventive: whose results are not deduced from the state of the art in an obvious or evident way for a person skilled in the art; and
- · industrially applicable.

Q: ARE THERE ANY SPECIFIC EXEMPTIONS TO PATENT ELIGIBILITY?

Exemptions include inventions whose commercial exploitation is contrary to the public order or contravenes legal provisions, particularly (Article 49 Federal Law on IP Protection):

- · procedures for cloning human beings and their products;
- procedures for modifying the germline genetic identity of the human being and its products when implying the possibility of developing a human being;
- · uses of human embryos for industrial or commercial purposes;
- procedures for modifying the genetic identity of animals that entail suffering without substantial medical or veterinary utility for humans or animals, and the animals resulting from these procedures;

- · plant varieties and animal breeds, except in the case of microorganisms; and
- essentially biological processes for obtaining plants or animals and the products resulting from these processes.

The above will not affect the patentability of inventions whose object is:

- a microbiological or other technical product or procedure;
- the methods of surgical or therapeutic treatment of the human or animal body and the diagnostic methods applied to them; and
- the human body in the different stages of its constitution and development, as well as the simple discovery of one of its elements, including the total or partial sequence of a gene.

Q: ARE THERE TECHNOLOGY-SPECIFIC ELIGIBILITY ISSUES THAT APPLICANTS MUST NAVIGATE (EG, IN SOFTWARE, BUSINESS METHODS, AI, MEDICAL DIAGNOSTICS, PHARMACEUTICALS OR MEDICAL PROCEDURES)?

Article 47 of the Federal Law on IP Protection establishes the following non-patentable technology:

- · scientific discoveries, theories or principles;
- · mathematical methods:
- schemes, plans, rules and methods for economic-commercial activities or businesses;
- · software;
- · biological and genetic material, as found in nature; and
- the juxtaposition of known inventions or product combinations, except when their combination cannot function separately or when their functions are modified to obtain a non-obvious result for a person skilled in the art.

Artificial intelligence cannot be considered as patentable as it is an abstract concept technology. However, when implemented in a process or real-life product constituting new features, this product or process may be patented before the Mexican Institute of Industrial Property (MIIP).

Q: WHAT ARE THE TIME AND COSTS INVOLVED IN SECURING A GRANTED PATENT? IS EXPEDITED EXAMINATION AVAILABLE? ARE REDUCED FEES AVAILABLE FOR CERTAIN APPLICANTS?

The average time to obtain a patent is three to five years from the national filing date. However, costs might vary depending on, among other things:

- · the length of the application;
- · translation costs;
- the official fee for the number pages in excess of 30; and
- · the number of office actions.

As an exercise, considering a medium-sized patent application with an average number of office actions, including the final fees and the first five annuities when granted, costs could be around \$8,000 to \$10,000. It must be considered that the MIIP allows a 50% discount for independent inventors, micro or small industry and educational institutions.

Additionally, the MIIP has an accelerated patent procedure, which aims to speed up the substantive examination of patent applications.

Q: WHAT ARE ANY SPECIFIC REQUIREMENTS THAT A PATENT SPECIFICATION MUST MEET IN YOUR JURISDICTION?

The patent specification must:

- indicate the title of the invention and specify the technical field to which it refers;
- indicate the prior art known to the applicant to which the invention belongs and cite the documents that describe the prior art; and
- detail the invention in clear and precise terms to allow a thorough understanding of the technical problem to be solved, exposing the advantageous effects of the invention with respect to the state of the art.

On the other hand, the specification should:

- · be concise, but as complete as possible;
- comprise connection with the figures, referencing them and the parts from which they are constituted;
- indicate the best-known method or way proposed by the applicant to carry out the pursued invention; and
- clearly indicate when it is not evident from the specification or nature of the invention, the way that it can be produced or used, or both.

Q: WHAT RULES GOVERN THE FILING OF PROVISIONAL APPLICATIONS, CONTINUATIONS OR CONTINUATIONS-IN-PART, DIVISIONALS, OR ANY OTHER SPECIAL TYPE OF APPLICATION?

Divisional applications must be submitted with the patent specification, claims and drawings, avoiding:

- the modification of the invention contemplated in the main case;
- pursuing a different invention than the one pursued in the main application; and
- containing no additional subject matter or giving a greater scope than the application initially filed.

In this respect, the new Federal Law on IP Protection modified its criteria when submitting voluntary divisional applications derived from prior divisional applications, in which case, they will not be accepted by the MIIP unless an explicit requirement to divide the subject matter is issued by means of a substantial examination office action.

The concept of 'continuations-in-part' does not exist in Mexico as it comprises additional subject matter to that filed originally with the main application. Provisional applications or any other type of different patent application are not contemplated.

Q: WHAT DO APPLICANTS NEED TO KNOW ABOUT OFFICE ACTIONS AND PATENT EXAMINER INTERVIEWS?

If, during substantive examination, the examiner notices any impediment for granting the patent, the MIIP may require the applicant within two months (extendible by a further two months) to file information and documentation and/or modify what is deemed appropriate. Likewise, the examiner might issue up to four office actions before the issuance of the final rejection or notice of allowance.

Regarding the examiner interviews, since the covid-19 pandemic crisis started, the MIIP has not accepted interviews with examiners.

Q: ARE THERE ANY RECENT EXAMINATION TRENDS THAT PATENT APPLICANTS NEED TO BE AWARE OF?

Regarding the MIIP criteria in respect to acceptance of divisional applications derived from another divisional application, they have not been rejected initially in the formality examination as they are currently handled under the criteria of the substantive examiners, who will have to analyse each case. Negotiation is ongoing, and it is anticipated that a new practice will be put in place.

Q: IS THERE ANYTHING ELSE ABOUT THE PATENT FILING PROCESS THAT APPLICANTS SHOULD KNOW?

In recent years, patent applications have been increasingly prosecuted online, and applicants should consider that once a patent application is filed online, it must be processed under the same system, meaning that it will not be possible to migrate to a different one. Furthermore, although there has been migration to an e-filing system, all signatures for the provided documents must be autograph signatures, as DocuSign is not accepted by the MIIP.

Additionally, a complementary certificate has emerged, establishing that when there are unreasonable delays (ie, delays of more than five years) directly attributable to the MIIP between the filing date and the grant of the patent, a complementary certificate may, at the request of the interested party, be granted to adjust the validity of patent. However, the complementary certificate's validity may not exceed five years.

Q: IS UTILITY MODEL OR PETTY PATENT PROTECTION OR AN EQUIVALENT AVAILABLE IN YOUR JURISDICTION? IF SO, HOW DOES THE SYSTEM WORK AND UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE USING IT?

Utility model protection is available in Mexico. This type of protection, based on the Federal Law on IP Protection, establishes that new and industrially applicable models will be registrable. It also considers objects, utensils, devices and tools to be included in utility patents that, as a result of modifications in their arrangement, configuration, structure or shape, present a different function with respect to integrating parts or advantages for their use.

Also, the applicant may transform a patent application into a utility model registration and vice versa, when it is inferred from the content of the application that it does not fulfil what is requested of it.

Utility model registration is advisable when what the applicant intends to protect is a modification to an existing device or tool to improve performance.

WHAT ARE THE MAJOR ADMINISTRATIVE PROCEDURES IN YOUR JURISDICTION?



Q: HOW CAN APPLICANTS APPEAL PATENT OFFICE DECISION?

If the patent authority issues an act or resolution putting an end to a process or instance, the applicant may file a motion of review before the authority within 15 working days, which will be resolved by its hierarchical superior.

The motion of review is the right procedural moment to offer further evidence and to suspend the execution of the challenged act when expressly requested by the appellant, on the assumption that it is admitted by the respective authority.

If the hierarchical superior issues a final resolution but the appellant does not agree, the corresponding annulment action may be filed before the IP Chamber of the Federal Court of Administrative Justice within 30 business days, and it may be resolved by recognising the validity of the challenged act or by declaring the nullity of the resolution.

Q: ARE OPPOSITIONS AVAILABLE PRE-GRANT OR POST-GRANT? WHAT RULES GOVERN STANDING TO OPPOSE A PATENT AND THE OPPOSITION PROCESS?

Mexican patent legislation does not establish oppositions. However, the MIIP may receive information from third parties regarding whether an application complies with the patentability requirements for its potential grant. Such information must be submitted within two months counted from the application's publication in the Official Gazette; in this case, the Patent Office may consider such information as technical support documentation for the substantive examination process.

This mechanism cannot be considered an opposition process, as the law eliminates the quality of interested party to whoever submits the information, and the MIIP is not obliged to decide on the scope of the informant's request.

Q: WHAT ARE THE PROCESSES FOR RE-EXAMINATION OF A PATENT?

Mexican patent legislation does not provide for re-examination. Once a patent is denied, it cannot be re-examined.

Q: WHAT IS THE PROCESS FOR INVALIDATION OR REVOCATION OF A PATENT? WHO HAS STANDING TO REQUEST INVALIDATION? HOW LONG DO INTER PARTES INVALIDATION CASES TAKE?

The process for revoking a patent is to file a declaration of nullity.

This declaration can be requested by a third party or by the MIIP **ex officio**, at any time after the patent publication of the patent in the Official Gazette.

According to Article 154 of the Federal Law on IP Protection, it must be based on one of the following grounds:

- the protected subject matter is not considered patentable or is extended beyond its scope of protection;
- the applicant does not disclose the invention in a clear and complete way;
- the claims exceed the disclosed subject of the application;
- the priority right has been wrongfully recognised and its novelty has been unduly determined; and
- the patent has been granted to someone who did not have the right to obtain it.

Q: HOW CAN OPPOSITION, RE-EXAMINATION OR INVALIDATION DECISIONS BE APPEALED?

Considering that the Mexican patent legislation does not establish an opposition process with respect to patents, and the submission of third-party observations does not oblige the MIIP to rule on its scope, there would be no resolution to appeal.

On the other hand, the declaration of nullity may be appealed within 15 business days by filing a motion of review, or within 30 business days by filing an annulment action.

Q: IS ADMINISTRATIVE ENFORCEMENT OF PATENTS POSSIBLE?

Administrative enforcement of patents is possible through an administrative declaration of infringement, which may be enforced by the MIIP *ex officio*, or at the request of whoever has and proves legal interest (Article 329, Federal Law on IP Protection).

The MIIP will carry out an analysis, eliminating violations to the patentee's rights (Article 344, Federal Law on IP Protection) by enforcing:

- the withdrawal of the infringing merchandise from circulation;
- the prohibition of its commercialisation or use;
- the suspension of its import, export or transit and rendering of the service; or
- the closing of establishments and condemnation of the infringer to pay damages.

As a result, involved traders or suppliers will be obliged to refrain from selling the infringing assets as of the date on which they are notified of the administrative resolution, as well as producers, manufacturers, importers and distributors, who will be responsible for immediately recovering the products placed on the market.

O: DOES YOUR JURISDICTION GRANT PATENT-TERM EXTENSIONS?

Patent-term extensions are not allowed in Mexico. However, the patent owner may request a one-time supplementary certificate of a maximum of five years to adjust the patent term when there are unreasonable delays directly attributable to the MIIP, resulting in the unnecessary extension of the patent procedure for more than five years.

Accordingly, a request must be filed independently when complying with the patent issuance fee, and any application filed after that time will be considered extemporaneous and dismissed outright.

Q: IS THERE ANYTHING ELSE ABOUT PATENT ADMINISTRATIVE PROCEDURES THAT PATENT OWNERS AND CHALLENGERS SHOULD KNOW?

There is a conciliation procedure before the MIIP, so that the parties reach an agreement and put an end to the administrative declaration of infringement, granted the character of *res judicata* with enforcement. However, the Patent Office will not pronounce itself on substantive matters, so the parties will be responsible for the agreements adopted during the negotiations. It may be requested by either party at any stage of the administrative declaration proceeding. If the resolution of the dispute has not been issued, however, the opposing party must agree to the initiation of the conciliation by accepting the initial proposal of the applicant or by submitting a counterproposal. This will not suspend the substantiation of the administrative declaration of infringement.





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HOW DO YOU GET A PATENT IN YOUR JURISDICTION?

Q: WHAT TYPES OF PATENT ARE GRANTED IN YOUR JURISDICTION, AND WHAT RIGHTS DO THEY CONFER ON OWNERS?

National Dutch and European patents are governed by the Dutch Patent Act 1995. The act and the courts have sought to harmonise Dutch patent practice with the European Patent Convention (EPC).

Dutch national patents are automatically granted through a registration system, without undergoing substantive examination.

There are generally two ways to obtain patent protection in the Netherlands:

- by filing a national patent application with the Dutch Patent Office (DPO); or
- by validating a patent granted by the European Patent Office (EPO) in the Netherlands.

Either is a utility patent, with a term of 20 years from the filing date. There are no utility models or petty patents available in the Netherlands.

Rights of the patentee are defined in Articles 53 and 73 of the Patent Act and include direct infringement, both literal or by way of equivalence, as well as indirect or contributory infringement.

The act principally defines two types of infringement. Exclusive rights include, in or for their business:

- to manufacture, use, place in circulation, sell, rent out, deliver or otherwise trade in a
 patented product or for any of the aforementioned purposes in the Netherlands or
 Netherlands Antilles (Curaçao, St Maarten, Saba, St Eustatius and Bonaire, but not
 Aruba) to offer, import or stock the patented product; and
- to apply a patented process or to use, put into circulation, sell, rent out, deliver or otherwise trade in the product obtained directly by the application of that process or to offer, import or stock such product for any of the aforementioned purposes in the Netherlands or Netherlands Antilles.

In the case of indirect or contributory infringement, a patentee may institute the claims against any person who offers means relating to an essential element of the invention for the application of the patented invention in the Netherlands or Netherlands Antilles.

In addition, a patent owner may claim reasonable compensation from any person for acts referred to above during the period between publication and grant of a patent.

Q: WHAT INVENTIONS ARE ELIGIBLE FOR PATENT PROTECTION IN YOUR JURISDICTION?

Dutch patent law is closely harmonised with the EPC and it follows the same eligibility requirements. Patentable inventions are to be granted for any inventions, in all fields of technology, provided that they meet three conditions – they must:

- be novel;
- · involve an inventive step; and

be capable of industrial application.

In addition, the invention must be sufficiently disclosed and described clearly in the patent.

Q: ARE THERE ANY SPECIFIC EXEMPTIONS TO PATENT ELIGIBILITY?

In line with the EPC, certain subjects are not considered inventions under the Patent Act, including:

- · discoveries, scientific theories or mathematical methods;
- · aesthetic creations;
- schemes, rules or methods for performing mental acts, games or business methods, or computer programs as such; and
- · presentations of information.

Q: ARE THERE TECHNOLOGY-SPECIFIC ELIGIBILITY ISSUES THAT APPLICANTS MUST NAVIGATE (EG, IN SOFTWARE, BUSINESS METHODS, AI, MEDICAL DIAGNOSTICS, PHARMACEUTICALS, MEDICAL PROCEDURES, ETC)?

The Patent Act also excludes inventions from patentability, including:

- the human body in the various stages of development;
- the discovery of parts of it that include sequences or partial sequences of the genome, plants and animal races;
- · predominantly biological methods; and
- methods for the treatment, diagnosis or therapy of the human or animal body.

Further, the act defines certain methods as being contrary to public policy and morale as not being subject to patents. Further excluded from patentability are inventions infringing on the Convention of Biological Diversity of Rio de Janeiro.

The above exceptions are usually interpreted narrowly, allowing substances or compositions for use in any treatment of the human or animal body by surgery, therapy or diagnostic methods practised thereon to be patented as first or further medical uses. Medical diagnostic methods can be patented if they are performed *ex vivo*. The restrictions also apply only so far as they concern the subjects or methods as such. This means that, for example, a computer program can be patented if it is used in an otherwise eligible product or method invention.

Q: WHAT ARE THE TIME AND COSTS INVOLVED IN SECURING A GRANTED PATENT? IS EXPEDITED EXAMINATION AVAILABLE? ARE REDUCED FEES AVAILABLE FOR CERTAIN APPLICANTS?

If more than acquiring a filing date is desired, Dutch national patents require:

- an official €80 digital filing fee; and
- a €100 search fee for a 'national type' search or a €794 fee for an 'international type' search (the latter executed by the EPO).

An international search entitles a partial or full refund of the search fee for a subsequent European or Patent Cooperation Treaty application. There are no claim, page or grant fees,



while annuities start on the fourth year (and only after grant) at a modest \leq 40, and increase by \leq 60 to \leq 100 per year until expiry. A Dutch national patent may, therefore, over its entire lifespan, incur official costs as low as \leq 15,000.

For validation of European patents, costs involve translations, a €25 official fee and annuities as above.

The filing fee must be paid at filing, whereas the search fee may be paid within 13 months of the earlier of the priority date or the filing date. After 18 months, the application or the already granted patent will be published in the patent register.

Publication and grant can be expedited on written request of the applicant after receipt of the search report. Patents granted within six to seven months of filing are not unusual.

Q: WHAT ARE ANY SPECIFIC REQUIREMENTS THAT A PATENT SPECIFICATION MUST MEET IN YOUR JURISDICTION?

Description and claims can initially be filed in any language, but to be eligible for grant, the specification must be translated into English or Dutch, and Dutch-language claims must be submitted within three months of filing.

Q: WHAT RULES GOVERN THE FILING OF PROVISIONAL APPLICATIONS, CONTINUATIONS OR CONTINUATIONS-IN-PART, DIVISIONALS OR ANY OTHER SPECIAL TYPE OF APPLICATION?

There are no provisional applications. However, Dutch patent applications may be filed without paying official fees, receiving a filing date if meeting minimal formal requirements. Official copies of such priority filings are available on request, and the DPO is also party to the Digital Access Service (DAS) of the WIPO, permitting applicants to request and use DAS codes.

If multiple inventions have been identified in the search report, only the first invention stated in the claims will be subject to patent protection. Unlike in, for example proceedings before the EPO, it is not possible to pay further search fees. The applicant may file divisional applications, based on the parent application and enjoying priority and filing dates thereof, taking care not to add subject matter going beyond the content of the originally filed application. Divisional applications are considered independent applications, requiring a separate search report. Those applications must be filed prior to publication of the granted parent application, but an applicant always has the opportunity to file within two months of issuance of the search report. Applicants are also afforded an opportunity to amend a patent application in this period. The two-month period after issuance of the search report may be extended by a further two months on request.

Q: WHAT DO APPLICANTS NEED TO KNOW ABOUT OFFICE ACTIONS AND PATENT EXAMINER INTERVIEWS?

The only office actions issued will concern formal matters; there is no examination on the merits.

Q: ARE THERE ANY RECENT EXAMINATION TRENDS THAT PATENT APPLICANTS NEED TO BE AWARE OF?

This is not applicable in the absence of a substantive examination process.



Q: IS THERE ANYTHING ELSE ABOUT THE PATENT FILING PROCESS THAT APPLICANTS SHOULD KNOW?

Search results for priority founding applications are usually available within five to nine months. It is recommended to pay the search fee at filing to ensure that the search report will be available well before the end of the priority period.

For European patents to come into force in the Netherlands, validation is required within three months of grant. Dutch-language claims must be filed and, if German or French is the language of the proceedings at the EPO, specification translations into Dutch or English should be filed. Care should be taken to re-validate limited claims or those maintained in amended form, as the amended or limited European patent will otherwise lapse.

Q: IS UTILITY MODEL OR PETTY PATENT PROTECTION OR AN EQUIVALENT AVAILABLE IN YOUR JURISDICTION? IF SO, HOW DOES THE SYSTEM WORK AND UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE USING IT?

There are no utility models or petty patents available in the Netherlands.

Q: UNDER WHAT CIRCUMSTANCES WOULD YOU ADVISE A NATIONAL PROSECUTION TO SECURE PROTECTION IN YOUR JURISDICTION RATHER THAN GOING DOWN THE EPO ROUTE?

Applying for and maintaining a Dutch national patent is cost and time-efficient and provides an excellent basis for a subsequent international application owing to the high quality and refundability of the search fee when using the EPO as a searching authority in a subsequent filing.

Dutch patents are automatically granted through a registration system. This system offers a fast and convenient procedure at comparatively low cost. Even though merits of a patent will ultimately be tested at court, a valid patent will afford the same protection as European patents within the Netherlands.

Dutch national patents cover not only the European part of the Netherlands, but also include the Caribbean islands of Curação, St Maarten, Saba, St Eustatius and Bonaire. These jurisdictions are not available under a European patent validated in the Netherlands.

WHAT ARE THE MAJOR ADMINISTRATIVE PROCEDURES IN YOUR JURISDICTION?

Q: HOW CAN APPLICANTS APPEAL PATENT OFFICE DECISION?

There are relatively few administrative procedures available in the absence of substantive examination.

Office actions are usually issued only with respect to formal aspects of an application.

Patent office decisions regarding formal objections or concerning reinstatement can be first addressed directly at the DPO, and, if needed, DPO decisions can be appealed at an administrative court of law at The Hague.

Q: ARE OPPOSITIONS AVAILABLE PRE-GRANT OR POST-GRANT? WHAT RULES GOVERN STANDING TO OPPOSE A PATENT AND THE OPPOSITION PROCESS?

Pre-grant or post-grant oppositions are not available. Patent revocation requires a procedure on the merits at the District Court of The Hague. Dutch and EPO patents in the Netherlands can be partially or completely revoked within the same procedure, requiring no bifurcation.

Q: WHAT ARE THE PROCESSES FOR RE-EXAMINATION OF A PATENT?

Re-examination of a patent is not applicable in the Netherlands; courts have the exclusive jurisdiction of assessing (partial) validity or a patent.

Q: WHAT IS THE PROCESS FOR INVALIDATION OR REVOCATION OF A PATENT? WHO HAS STANDING TO REQUEST INVALIDATION? HOW LONG DO INTER PARTES INVALIDATION CASES TAKE?

Patent-related proceedings (both interim and on the merits) are under the exclusive jurisdiction of the courts of The Hague. Cases in the first instance are heard by the District Court and appeals by the Court of Appeal of The Hague. Both courts have a specialist patent division, consisting of experienced judges, some with technical training.

Besides patent proceedings on the merits relating to infringement or invalidity, it is also possible to request declarations of non-infringement, compulsory licences, challenges of patent ownership and declaratory judgments that a certain product was already known in the prior art (known as '*Arrow*declarations'). This offers the opportunity of early certainty about the infringing nature of its own product before entering the market, even before patent grant.

Before starting infringement proceedings, the exchange of warning letters is advised to avoid the consequences of cost orders or damages compensation.

Dutch law provides no mandatory procedural steps before claiming invalidity of a European patent. However, it is different for Dutch national patents, where a party prior to wishing to submit a claim for invalidity must obtain a patentability (nullity) opinion from the DPO. This opinion must be submitted together with the writ of summons in invalidity proceedings, or during a response in the case of a counterclaim.

The requesting party and patentee are allowed to comment in the advice procedure at the DPO. A patentee is afforded at least one opportunity to respond and may furthermore amend its claims. Once the written procedure and optional oral proceedings for the opinion have been completed, the DPO issues an opinion.

STANDING

In principle, while any party may request a revocation, the courts may deny standing to parties that cannot show a relation to or adverse effect by the patent rights. While not being fully crystallised in case law, the Dutch courts generally favour parties identifying themselves.

INTERIM INJUNCTION PROCEEDINGS

In the Netherlands, *inter partes* interim injunction proceedings are often used in the case of urgent patent enforcement. Decisions are given fairly quickly, while still allowing for a thorough assessment of the case. Such proceedings generally last one to three months. In exceptionally urgent cases, decisions may be rendered in the course of weeks or, highly exceptionally, in days.

Although decisions are temporary, as proceedings on the merits must follow within six months, the assessment is usually thorough. If a serious, non-negligible chance exists that a patent would be found invalid or not infringed, provisional measures will usually be denied.

Q: HOW CAN OPPOSITION, RE-EXAMINATION OR INVALIDATION DECISIONS BE APPEALED?

Once a judgment is rendered, decisions can be appealed at the Court of Appeal in The Hague, where the case can be reviewed in full. Once a decision has been rendered, both parties can request the case to be reviewed again by the Dutch Supreme Court, where only matters of law and legal reasoning will be assessed, not the underlying facts.

Q: IS ADMINISTRATIVE ENFORCEMENT OF PATENTS POSSIBLE?

Criminal court proceedings for grave cases of infringement could be initiated by the public prosecutor; however, in practice, patent infringement in the Netherlands is rarely dealt with in criminal proceedings.

Administrative enforcement of patents is available with the Dutch Customs Authority, which can and will monitor import and trade of infringing goods and can seize such goods on request.

Q: DOES YOUR JURISDICTION GRANT PATENT-TERM EXTENSIONS?

The only patent term extensions are supplementary patent certificates, which may be applied for concerning the active ingredients of pharmaceuticals or agrochemicals, enabling an extension of up to five years (or up to five-and-a-half years for paediatric pharmaceuticals) after the expiry date.

Q: IS THERE ANYTHING ELSE ABOUT PATENT ADMINISTRATIVE PROCEDURES THAT PATENT OWNERS AND CHALLENGERS SHOULD KNOW?

PROCEEDINGS ON THE MERIT

In regular proceedings on the merits, parties may exchange several rounds of briefs, followed by a hearing, usually taking up to 20 months. A special fast-track procedure is available that forces parties to present arguments and evidence at the outset and limiting the number of exchanges. Judgments are often obtained within 14 months.

Patent infringement proceedings start with a writ of summons, setting out the claimant's position and relief requests. In response, a defendant can file a defence statement and may also enter a counterclaim within the same procedure, usually to the invalidity of the patent.

A patentee may amend the patent during litigation by submitting auxiliary requests during the proceedings, both in the first and second instance. This must be done early, as late filing will lead to refusal by the court. During appeal, a limitation conducted after exchange of the main court briefs will, in general, not be permitted.

Finally, a patentee may, unilaterally, relinquish its patent in whole or in part, by amending claims, by submitting a deed to that effect in the patent register. Such registrations cannot proceed without the consent of third parties who have registered rights, licences or claims in legal proceedings in that same patent register. For European patents, a patentee may also avail themselves of the limitation procedure at the EPO.

RELIEF. REMEDIES AND COST COMPENSATION

If the court finds for infringement, remedies may include injunctions, accounting for infringing products or processes, including:

- a duty to provide information on the scope of the infringing acts;
- recall and destruction of infringing products;

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 - · rectifications; and
 - · compensation of damages or surrender of profits.

Relief will typically be granted notwithstanding appeal, but a winning party should be careful in enforcing, as it will be liable to bear the damage caused by measures revoked in appeal.

A successful party to a patent infringement action is entitled to recover reasonable and proportionate costs from the losing party. The law sets out indicative rates for patent litigation, whereby fees are capped at a maximum amount, depending on the complexity of a case.



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