The Patent Prosecution Review

2024

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The first edition of theIAM Patent Prosecution Review takes a wide-ranging view of best strategies for securing patents in the key regions of the Americas, the Asia-Pacific, and Europe, the Middle East and Africa. The review combines on-the-ground knowledge and analytic insight to offer an unparalleled deep dive into the prosecution landscape in specific markets.

Generated: July 6, 2024

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Specialist Chapter: How to Assess Patent Eligibility of AI Inventions in China

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Summary

IN SUMMARY

In China, patent eligibility of AI inventions is assessed by examining in sequence whether the AI inventions fall under the rules and methods for mental activities and whether they constitute a technical solution. An AI invention claim can pass the examination as to mental activities as long as it contains at least a technical feature. The 'three elements of technology' test is then applied to examine whether the claim constitutes a technical solution, requiring the claim to contain some technical means applying the laws of nature to solve a certain technical problem, with some technical effects achieved.

DISCUSSION POINTS

- AI invention
- Patent eligibility
- Algorithmic features
- Technical features
- Mental activities
- Technical solutions

REFERENCED IN THIS ARTICLE

- Article 2, paragraph 2 of the file:///Users/isabel.holme/Downloads/
- Patent Law of the People's Republic of China
- Article 25, paragraph 1, item 2 of the Patent Law of the People's Republic of China
- Part II, Chapter 9, section 6 of the revised 'Guidelines for Patent Examination' (2010)
- China National Intellectual Property Administration

Artificial intelligence (AI) technology is currently undergoing revolutionary development. Generally, 'artificial intelligence' can be defined as 'theories, methods, technologies and application systems that utilize digital computers or machines controlled by digital computers to simulate, extend and expand human intelligence, perceive the environment, acquire knowledge, and use the knowledge to obtain optimal results'[1]. Since AI technology is centred around the simulation of how humans perceive and process information, like hearing and vision, it has been innovatively applied to fields such as voiceprint recognition, facial recognition, driverless cars, intelligent customer service chatbots, machine translation and medical image processing.

The essence of AI technology is algorithms. As a result, most, if not all AI inventions are solutions involving algorithms, although algorithms per se are explicitly excluded, as rules and methods for mental activities, from patent-eligible subject matters under Chinese patent law.[2] With patent applications relating to new AI technologies surging, the question of how to assess the patent eligibility of AI inventions has become an important issue of concern to the Chinese patent industry as well as to innovation subjects.

RULES FOR EXAMINING PATENT ELIGIBILITY OF AI INVENTIONS

In the revised 'Guidelines for Patent Examination', which were issued by the China National Intellectual Property Administration (CNIPA) on 31 December 2019 and entered into force on 1 February 2020, a new section titled 'Provisions on the examination of patent applications for invention containing algorithmic features or features of business rules and methods' was added for patent applications for inventions relating to AI, Internet Plus, big data and blockchain.[3] This new section provides detailed rules for examining patent applications for inventions relating to these topics and aims to standardise the examination criteria of such applications.

According to this new section of the revised 'Guidelines for Patent Examination', the patentability examination of patent applications for AI inventions will be conducted in order as follows:

- examination of patent eligibility; and
- examination of novelty and inventiveness.

Specifically, for the examination of patent eligibility, whether a claim of a patent application falls under the rules and methods for mental activities as stipulated in article 25, paragraph 1, item 2 of the Chinese Patent Law (article 25.1 (2)) will first be examined. If the claim, considered as a whole, does not fall under the rules and methods for mental activities, then the examination will proceed to determine whether it constitutes a technical solution as referred to in article 2, paragraph 2 of the Chinese Patent Law (article 2.2).

The CNIPA emphasises that the eligibility examination of patent applications for AI inventions shall follow such criteria that the examination shall be carried out on the solution for which the patent protection is sought, meaning the solution defined by the claim. The examination of such solution shall be conducted in a way that ensures all of the contents recorded in the claim are taken as a whole to analyse the technical means involved, the technical problems solved and the technical effects obtained, instead of simply breaking the claim down into technical features and algorithmic features or features of business rules and method (BM features), which are then evaluated separately.

In particular, in the examination under article 25.1(2), if a claim contains one or more technical features in addition to algorithmic features or BM features, the claim, viewed as a whole, is deemed not to fall under the rules and methods for mental activities as stipulated in article 25.1(2), and should not be excluded from patent-eligible subject matters. The claim is considered to fall under the rules or methods for mental activities only if it is drawn to just an abstract algorithm, or simply BM features, and does not contain any technical features. For example, a mathematical modelling method based on an abstract algorithm that does not contain any technical features falls into the rules and methods for mental activities, and is thus ineligible for patent protection.

In the examination under article 2.2, it is necessary to consider all the features recited in the claim as a whole and apply the 'three elements of technology' test. According to this test, if the claim contains some technical means that apply the laws of nature to solve a technical problem and thereby achieves some technical effects in compliance with the laws of nature, then the claimed solution constitutes a technical solution as referred to in article 2.2. In practice, a claim on an AI invention can pass the examination under article 2.2, provided that the AI algorithm recited in the claim is applied in a specific technical field to solve a technical problem with some technical effects obtained. Illustratively, the AI invention will be

deemed as a technical solution if the steps concerning the algorithm recited in the claim are each closely related to the technical problem to be solved (eg, the data processed by the algorithm is data with a concrete technical meaning in the technical field), if the execution of the algorithm can directly reflect the process of applying the laws of nature to solve a certain technical problem and if some technical effects can be achieved.

EXAMPLES OF PATENT ELIGIBILITY EXAMINATION OF AI INVENTIONS

Example 1

A claim drawn to a model training method reads as follows.

A method for training a model comprising a first sub-model, a second sub-model and a third sub-model, the method comprising:

- obtaining training samples comprising a labelled sample set and an unlabelled sample set; and
- training the first sub-model, the second sub-model and the third sub-model using the training samples to obtain the trained model.

For the examination of the patent eligibility of the claim, firstly it will be examined to check whether the claimed subject matter falls under the rules and methods for mental activities as stipulated in article 25.1(2), and if it does not, then it will be examined to check if it constitutes a technical solution as referred to in article 2.2.

In this example, the claim contains only algorithmic features, so it would be rejected as falling under the rules and methods for mental activities as stipulated in article 25.1(2).

Example 2

The claim of Example 1 is redrafted to read as follows.

A method applied to a computer for training a model comprising a first sub-model, a second sub-model and a third sub-model, the method comprising:

- obtaining training samples from a labelled sample set and an unlabelled sample set stored in a storage space; and
- training the first sub-model, the second sub-model and the third sub-model using the training samples to obtain the trained model.

In this example, the claim contains some technical features like 'a computer' and 'a storage space' in addition to the algorithmic features, so it shall not be rejected as falling under rules and methods for mental activities as stipulated in article 25.1(2).

However, the claim of Example 2 fails to be applied in a specific technical field to solve a technical problem. In particular, the objects processed by the algorithmic steps – 'a labelled sample set', 'an unlabelled sample set', 'training samples' and 'model' – are all abstract mathematical concepts rather than data with a concrete technical meaning in the technical field, and the execution of the algorithm fails to directly reflect the process of applying the laws of nature to solve a certain technical problem with any technical effects obtained. Therefore, it would fail to meet the 'three elements of technology' test, so the claimed method in Example 2 is not a technical solution as referred to in article 2.2.

Example 3

The claim of Example 1 is then redrafted to read as follows.

A method applied to a computer for training a model adapted for detecting internet abnormal access behaviour and comprising a first sub-model, a second sub-model and a third sub-model, the method comprising:

- obtaining training samples from a sample set labelled as abnormal access data or as normal access data and an unlabelled sample set that are stored in a storage space; and
- training the first sub-model, the second sub-model and the third sub-model using the training samples to obtain the model for detecting internet abnormal access behaviour.

The claimed method of Example 3 is directed to solve a technical problem of how to detect internet abnormal access behaviour in the technical field of the internet. The objects processed by the algorithmic steps, such as 'a sample set labelled as abnormal access data or as normal access data' and 'the model for detecting Internet abnormal access behaviour', are data with a concrete technical meaning in the relevant technical field, and the execution of the algorithm directly reflects the process of applying mathematics that belongs to the laws of nature to solve the technical problem of how to detect internet abnormal access behaviour with certain technical effects obtained. Therefore, the claimed method of Example 3 passes the 'three elements of technology' test as it constitutes a patent-eligible technical solution, as referred to in article 2.2.

CONCLUSION

From the above examples, it can be understood that according to the current practice of examining the patent eligibility of AI inventions in China, a relatively low-threshold criterion is used in the examination of whether a claim falls under the rules and methods for mental activities as stipulated in article 25.1(2). As long as the claim contains a technical feature or technical features, it can usually pass the examination. However, the "three elements of technology" test, which is a relatively high-threshold criterion, is also applied to examine whether a claim constitutes a technical solution as referred to in article 2.2. This test requires the claim to contain some technical means applying the laws of nature to solve a certain technical problem, with some technical effects in compliance with the laws of nature achieved thereby.

Endnotes

1 See the 'Artificial Intelligence Standardization White Paper' (2018 edition), edited by the Chinese Electronics Standardization Institute. ^ Back to section

2 See article 25, paragraph 1, item 2 of the Patent Law of the People's Republic of China. ^ Back to section

3 See Part II, Chapter 9, section 6 of the revised 'Guidelines for Patent Examination' 2010. ^ Back to section

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Specialist Chapter: Why a Robust Specification is Crucial for Satisfying Disclosure Requirements for Chemical and Non-chemical Inventions

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Summary

IN SUMMARY

This article discusses key considerations while preparing a patent application that meets the standards of the Indian Patents Act. It also emphasises the significance of writing patent specifications that satisfy both sufficiency and best method criteria, and it gives recent judgments relating to the assessment of these factors for both chemical and non-chemical inventions. It further underlines the need to draft a specification that covers multiple embodiments, in order to give adequate support for possible divisional applications in the future.

DISCUSSION POINTS

- Importance of quid pro quo agreement in India
- Implications of article 29 of the TRIPS Agreement concerning sufficiency of disclosure and best method of performing an invention in India
- Enhanced efficiency and synergism according to the Indian Patents Act and the significance of supporting data
- 'Best method' consideration for non-chemical subject matters
- Interpretation of section 16 of the Indian Patents Act

REFERENCED IN THIS ARTICLE

- Communication Components Antenna Inc v Mobi Antenna Technologies
- Astrazeneca v Intas Pharma
- *Janssen Pharmaceuticals v by the Network of Maharashtra people living with HIV (NMP+) and Anr*
- Societe Des Produits Nestle SA v The Controller of Patents and Design and O rs
- BASF Corporation [2019] Australian Patent Office 34
- Titan Umreifungstechnik Gmbh and Co KG v Assistant Controller of Patents an d Designs and Ors
- Esco Corporation v The Controller of Patents & Designs
- Boehringer Ingelheim v The Controller Of Patents & Anr
- Syngenta v The Controller of Patents & Designs

INTRODUCTION: AN ART AND A SCIENCE

Drafting patent specifications is an art because it tells a story. A good story includes, among other aspects, a plot, development of each character, interaction between characters to resolve one or more conflicts in an unexpected yet tactful way, and a common theme (or a 'big idea') that runs through the entire story. Attention to detail is the hallmark of a story worth telling. Similarly, a patent specification tells the story of an invention. A good specification includes the rudiments of a good story.

Drafting a patent specification is also a science because it follows a set of scientific rules. The specification identifies a problem in the state of the art or a possible improvement over the existing technology, suggests a solution hypothesis (or multiple), explains the purpose and scope of the hypothesis, describes the testing of the hypothesis using drawings, charts, equations, examples, etc, and substantiates the hypothesis with data and evidence. Simply put, a patent specification sufficiently answers the why, how and what questions. The technical problem of the existing technology and the solution offered by the inventors typically answer the why question. The how question can be answered by providing at least one exemplary embodiment that explains the best method to perform the invention. Clear and succinctly worded 'claims' answer the what question by including the lowest number of interdependent elements needed to distinguish the invention from the closest prior art.

QUID PRO QUO

The function of the patent system has evolved over the centuries and has shifted its character from an exclusive privilege to a social contract.[1] The patent system now serves to promote the dissemination of knowledge pertaining to innovations in exchange for exclusive rights. Since a patent is now a quid pro quo agreement, the significance of drafting a robust patent specification cannot be emphasised enough.

SUFFICIENCY OF DISCLOSURE AND BEST METHOD REQUIREMENTS

The sufficiency of disclosure and the best method of performing the invention are desideratum when constructing a robust specification. The need for stringent sufficiency of disclosure and best method requirements in India can be attributed to India's substantial import market. According to data released by the Indian government,[2] imports of commodities into India during 2021 and 2022 (April to January) increased by 62.68 per cent when compared with 2020 and 2021 (April to January).

As astutely observed by Bingbin,[3] developing countries (including India) have a growing need to import technologies. Therefore, the sufficiency and best method disclosure requirements will ensure that developing countries get access to those technologies with 'sufficient and valuable information'. Further, Bingbin envisages that the best method disclosure requirement may be beneficial to domestic companies to build newer technologies based on 'sufficient and pivotal information' in the patent specification.[4]

Also, article 29 of the https://www.wto.org/english/docs_e/legal_e/27-trips.pdfAgreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) stipulates that:

> … an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention ….

The TRIPS Agreement specifies that the 'sufficiency of disclosure' is a compulsory obligation and the 'best method/mode' requirement is optional. Within this broad requirement specified in the TRIPS Agreement, each jurisdiction may differ regarding interpretation as to what constitutes sufficiency and best mode.

Sufficiency of disclosure (equivalent to the enablement requirement in some countries) assesses whether a patent application describes an invention such that one skilled in the art

can make and use the claimed invention without undue experimentation. Sections 25(1)(g), 25 (2)(g) and 64(1)(h) of the Indian Patents Act 1970 state that failure to sufficiently and fairly describe the invention in the complete specification is a ground for opposition and invalidation of the patent.

The best method (best mode in some countries) for performing an invention requires that the invention, after the end of its patent term, 'can be exploited in equality of condition between the former holder and a third [interested] party'.[5] In the US, for example, although the United States Patent and Trademark Office may raise objections to the effect that the best mode of performing an invention has not been disclosed in the specification, the Leahy–Smith America Invents Act 35 USC 282 states that the failure to disclose the best mode shall no longer be a basis in patent validity or infringement proceedings.

The best method requirement in India is laid out in section 10(4)(b) of the Indian Patents Act, which states that every complete specification shall disclose the best method of performing the invention that is known to the applicant and for which they are entitled to claim protection. Further, section 64(1)(h) states that failure to disclose the best method of performing an invention that was known to the applicant is a ground for invalidation of a patent claim.

Therefore, according to the Indian Patents Act, a complete specification accompanying an application must meet both the sufficiency of disclosure (enablement) and best method (best mode) requirements, and failure to do so can be used as a ground to invalidate the patent.

ASSESSING SUFFICIENCY AND BEST METHOD

The guidelines issued by the Indian Patent Office (IPO) for examining pharmaceutical patent applications state the following:

> While assessing the sufficiency of disclosure … the best method for performing the invention known to the applicant is described so that the whole subject-matter that is claimed in the claims, and not only a part of it, must be capable of being carried out by a skilled person in the relevant art without the burden of an undue amount of experimentation or application of inventive ingenuity.[6]

Further, the guidelines state that:

> The description in the specification should contain at least one example or more than one example, covering the full breadth of the invention as claimed, which enable(s) the person skilled in the art to carry out the invention.

The guidelines also state:

> If the invention is related to product per se, description shall be supported with examples for all the compounds claimed or at least all the genus of the compounds claimed.[7]

Noting that the role of complete specifications is to 'teach' what the invention is, how the invention is to be made and how the invention is to be used, the Delhi High Court, in the matter of Communication Components Antenna Inc v Mobi Antenna Technologies also observed that:

> The criteria determinative of the sufficiency of disclosure … has to be construed impartially, when any of the grounds enumerated under Section 64 of the Act are invoked. The Court would be generally slow to construe patent specifications against the patentee.[8]

ENHANCED EFFICIENCY AND SYNERGISM

The enigma surrounding https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.html-section 3(d) and https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps3.htmlsection 3(e) of the Indian Patents Act is well known worldwide. To put it succinctly, a claimed substance's 'enhanced efficacy' in relation to a known substance's efficacy is evaluated under section 3(d), while a claimed composition's synergistic effects are evaluated under section 3(e). To establish technical advancement, enhanced efficacy or synergism, data and evidence should be included in the specification. The question before the courts has been on the timing of presenting such evidence. Should it be part of the original specification? Can it be provided during the prosecution of the application by way of affidavit?

The courts have previously ruled that post-priority date evidence disclosed subsequent to filing the application can be admissible only if the evidence confirms the existence of technical effect 'plausibly demonstrated' and 'found embedded' in the original specification (Astrazeneca v Intas Pharma[9]).

In the matter of Janssen Pharmaceuticals v by the Network of Maharashtra people living with HIV (NMP+) and Anr, the IPO found that the claims lacked inventive step and were not patentable under sections 3(d) and 3(e) of the Indian Patents Act. The invention pertained to a pharmaceutical composition including fumarate salt of bedaquiline for the treatment of a mycobacterial infection, particularly tuberculosis. During oral proceedings, the applicant had provided an affidavit to show a 159 per cent increase in bioavailability of the drug in its fumarate salt form over the base compound, and an intrinsic dissolution rate of the claimed salt double the rate of the non-salt form of the compound. The IPO observed that:

> [n]o data has been shown in the complete specification to substantiate that a combination of fumarate salt of Bedaquiline along with Tween 20 (wetting agent) would show surprising effect over the known composition of Bedaquiline on the treatment of a patient," and that "the applicant failed to disclose any evidence to support the statement made out regarding increase in bio-availability as well as rate of increase in dissolution profile of the composition.

The purported surprising effect of increased bioavailability as a consequence of increased solubility was not found convincing by the IPO. The IPO opined that the increased bioavailability as claimed by the applicant was an afterthought because there had been no discussion on this point in the original specification. The IPO stated that:

> [h]ad it been the only problem to be solved, all such findings could have been well documented and incorporated before the priority date of the application.-[10]

The IPO further observed that the inventor's affidavit, which the applicant filed only after the objections surfaced, did not provide adequate data for the claimed 159 per cent increased bioavailability. Although the IPO appears to have erred in rejecting the composition claims

under section 3(d), refusal of the application on the ground of inventive step and section 3(e) for lack of specific data in the disclosure seems to be consistent with Indian law.

In the matter of Societe Des Produits Nestle SA v The Controller of Patents and Design and Ors, the Delhi High Court set aside the objection of the Controller under section 3(e) as it was proved to be not sustainable. The invention related to a composition comprising dihomo-γ--linolenic acid (DGLA), which is known to exhibit anti-inflammatory properties. The synergistic effect of the claimed composition is the reduction of interleukin 4 (IL-4), known to be an anti-inflammatory cytokine, since excess production of IL-4 may cause tumours.

A detailed comparison between the IL-4 values of the control group, the DGLA 60 group, the NIF 2.14 group and the composition of the impugned application was provided in the specification. Other parameters, including IgE values, mast cells and IL-10 secretion in brachial lymph nodes, were also disclosed in the specification. The Delhi High Court correctly observed that:

> the appellant has provided extensive experimental data in the specification supported by examples as well as drawings showing the synergistic effect.[11]

SUPPORTING DATA AND ITS SIGNIFICANCE

A clear pattern emerges when analysing the judgments issued by the courts and the IPO in the cases of chemical- and pharmaceutical-related inventions. Indicative data in support of technical advancement, efficacy and synergism in the form of comparative examples, experimental data, charts and tabulation, etc, must be disclosed in the specification, preferably at the time of filing the application. Providing data post-filing, for instance to overcome an objection raised by the examiner, may be allowed entirely at the discretion of the examiner and only if the original description plausibly demonstrates, or reasonably points to, a hitherto unknown technical effect or advancement.

If the post-filing data significantly deviates from the original specification, the patent office will most likely decline to take the post-filing data into consideration when determining inventive step or sufficiency of disclosure. However, if the post-filing data corroborates the disclosure made in the original specification, the patent office can be persuaded to admit the data.

The approach of the IPO is not very different from that of other major patent offices. The Australian Patent Office, for instance, in the matter of BASF Corporation [2019] APO 34, following the guidance of a UK Supreme Court ruling, agreed that subsequent data cannot be a substitute for sufficient disclosure in the specification.[12] Japan and Korea are also disinclined to accept post-filing data for determining sufficiency of disclosure, although they can be persuaded to consider the same for establishing inventive step. On the other hand, countries like the USA, Europe and China are more liberal in accepting post-filing data for the purposes of establishing inventive step and for enablement (sufficiency) considerations.

In India, especially in cases where patents are sought for incremental innovations or derivatives of a known pharmaceutical composition, the requirement of data demonstrating therapeutic efficacy is sine qua non. Although incremental inventions may have 'huge potential for the development of drugs with superior health benefits',[13] in the absence of evidence to the contrary, they can potentially become an attempt at evergreening existing patents for the same base compound. One of the continuing challenges facing drug manufacturers is that the amount of qualitative and quantitative data required to

demonstrate enhanced efficacy of an incremental invention over the prior art remains subjective.[14] Also, the ambiguity of the language 'enhancement of the known efficacy' in section 3(d) could be addressed by way of further explanation or amendment 'which in turn would enable the protection of truly inventive innovations without exacerbating the chances of evergreening'.[15]

Applicants may find themselves in a quandary while deciding on when to file a patent application. Waiting for sufficient test data and examples before filing the application may run the risk of having a later priority date, thereby exposing the application to newer prior arts. Filing without sufficient supportive data and examples may invite objections on insufficiency of disclosure or lack of best method of working the claimed invention. Although there is no one-size-fits-all solution to this predicament, it would be prudent to provide sufficient information in the specification that can form a basis for any post-filing data filed during the prosecution of the application.

ASSESSING BEST METHOD FOR NON-CHEMICAL APPLICATIONS

While evaluating whether a patent application pertaining to a non-chemical subject matter includes the best method of performing the invention as known to the applicant (section 10(4)), the courts seem to employ a different yardstick. For instance, in the matter of Titan Umreifungstechnik Gmbh and Co KG v Assistant Controller of Patents and Designs and Ors, the Delhi High Court ruled that:

> there is no mandatory requirement to provide examples for non-chemical related inventions … furnishing of working examples [is] as an essential condition only in case of chemical related inventions. Thus, although working examples can be beneficial in assessing the patentability of an application, they are not strictly necessary ... Mere absence of working examples does not render the subject application liable for rejection.[16]

The Delhi High Court also mentioned that the controller, in order to satisfy themself, can ask the appellant to prove that their claims are supported with workings. In the case of non-chemical inventions, it is advisable to disclose the best method of performing the invention in the complete specification as an exemplary embodiment of the invention.

SUPPORT FOR PROSPECTIVE DIVISIONAL APPLICATIONS

The description and claims of a patent application should be drafted taking into consideration the unique requirements in India. As per certain recent judgments:

- the claims of the first application should define a plurality of inventions (Esco Corporation v The Controller of Patents & Designs)[17]; and
- the claims of the divisional application should have been present in the claims of the first application. A divisional application is not maintainable solely on the basis of disclosure made in the specification (Boehringer Ingelheim v The Controller Of Patents & Anr)[18].

However, a more recent judgment (Syngenta v Controller of Patents)[19] has revisited and challenged the Boehringer decision and has referred the matter to a Division Bench. The Division Bench will decide on the matter of maintainability of a divisional application based solely on the original disclosure.

Given the above developments governing divisional applications in India, it is important that the first application includes all possible embodiments – both significant and optional – to support a divisional application preferred in the future.

CONCLUSION

In any contentious proceeding, the patent specification comes under intense scrutiny. Applicants who disclose adequate information to meet the sufficiency and best method requirements are ensured full protection under the law and can successfully enforce their patents against infringers. Also, since the description and claims form the basis for deciding on the maintainability of a divisional application, it is prudent to draft the application with sufficient scope for pursuing divisional applications in the future.

Endnotes

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Australia: Computer-related Inventions, Patent Term Extensions and Stricter Examination Trends

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Summary

IN SUMMARY

No substantive changes in Australian patent law or practice have occurred recently, although it has been clarified that artificial intelligence may not be validly listed as an inventor on a patent. There is a general continuing trend for higher new patent filings in health technology fields. Anecdotally, Australian examiners appear to be applying support, enablement and manner of manufacture (patentability) requirements more strictly across a number of technology fields.

DISCUSSION POINTS

- Manner of manufacture continues to be a contentious issue for computer-implemented inventions
- Australian examiners are raising increasingly strict support, enablement and manner of manufacture objections
- Significant delays are being observed for commencement of examination in pharmaceutical, chemical, biotechnology and biotherapeutics fields
- For pharmaceutical related inventions, patent term extensions should be based on the earliest regulatory approval date regardless of whether the substance was developed by the patentee or a competitor

REFERENCED IN THIS ARTICLE

- Patents Act 1990 (Cth)
- *Commissioner of Patents v Ono Pharmaceutical Co Ltd [2022] FCAFC 39 (Ono)*
- *Merck Sharp & Dohme Corp v Sandoz Pty Ltd [2022] FCAFC 40 (MSD)*
- *Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents> [2022] HCA 29 (17 August 2022)*
- *Commissioner of Patents v Thaler [2022] FCAFC 62*

ELIGIBILITY

In Australia, a patent can be granted on a wide range of inventions such as pharmaceuticals, mechanical devices and consumer products. However, there are some exclusions. In particular, Australian law expressly states that human beings or the biological processes for their generation are not patentable.

Additionally, an invention must be a manner of manufacture within the meaning of section 6 of the Statute of Monopolies to be patentable subject matter,[1] the meaning of which has been developed through case law. In general, artistic creations, mathematical models and plans, schemes or purely mental processes are not held to be patentable.

Computer-implemented

Computer-implemented inventions can be patentable subject matter, subject to the case law developed for manner of manufacture. Numerous recent decisions have developed

the case law of what constitutes a manner of manufacture of a computer-implemented invention.[2] Current Australian Patent Office (APO) practice in assessing whether a computer-implemented invention is for a manner of manufacture typically involves identifying the substance of the claimed invention (ie, the contribution that the invention makes over the state of the art), and determining whether the substance lies within established principles of what does not constitute a patentable invention or lies outside of existing concepts of manner of manufacture,[3] utilising the following guidelines derived from case law:[4]

- whether the invention achieves a practical, tangible and useful result;
- whether the invention solves a technical problem within the computer or outside the computer or whether it results in an improvement in the functioning of the computer, irrespective of the data being processed;
- whether the claimed method merely requires generic computer implementation;
- whether the computer is merely an intermediary or tool for performing the method while adding nothing of substance to the idea;
- whether the ingenuity in the invention is in a physical phenomenon in which an artificial effect can be observed rather than in the scheme itself;
- whether the alleged invention lies in the way the method or scheme is carried out in a computer; and
- whether the alleged invention lies in more than the generation, presentation or arrangement of intellectual information.

Applicants for patents of computer-implemented inventions in Australia should therefore endeavour to highlight technical advantages and technical problems in the state of the art and include detailed technical descriptions of the invention in patent specifications.

Biotechnological And Medical

Claims in substance consisting of naturally occurring genetic information have been found to lack a manner of manufacture and are considered unpatentable.[5] However, methods of using naturally occurring genetic sequences have been found patentable, and transgenes comprising naturally occurring gene sequences operably connected to heterologous sequences are typically accepted by the APO. Biological materials including isolated micro-organisms and isolated peptides are patentable even when the same as naturally occurring counterparts as they are considered to be 'made'.

Both method of treatment claims and Swiss style claims are patentable in Australia.[6],-[7] European Patent Convention 2000 'for use' style claims are patentable in Australia but are not considered to be limited to the recited therapeutic use and are therefore often not valid. Such a claim may be converted to both a method of treatment claim and a Swiss style claim, which can be advantageous as there are different requirements to prove infringement of these claim formats.

EXAMINATION TRENDS

Chemical

There has been a trend in certain types of claims for chemical inventions having support and/or enablement objections raised against them.

Australian examiners generally object to claims with undefined optional substituents or medical use claims specifying broad treatments. Additionally, Australian examiners typically take the view that very small changes in the composition of an alloy or peaks of an x-ray diffraction (XRD) spectrum can result in materials having completely different physical properties. In view of this, support or enablement objections are generally raised against broad alloy claims that define hypothetical equivalent alloys that are not exemplified in the specification, or crystalline polymorph claims that are defined by reference to only a small number of peaks of their XRD spectrum.

Biotechnological

It is becoming increasingly difficult to obtain broad claims to antibodies in Australia. Objections are generally raised against claims that define an antibody by fewer than six complementarity-determining region (CDR) sequences, or that encompass variation within one or more CDR sequences. On the other hand, where the claimed antibody is defined by all six CDR sequences, it is generally sufficiently enabled as the CDRs can be synthesised and inserted into the various antibody frameworks as a matter of routine. Note, however, asserting that a claimed antibody is sufficiently enabled on this basis may raise issues for inventive step.

Claims directed to antisense oligonucleotides have recently been alleged to be claims to 'genetic information' per se, even though the claimed sequences are not present in the genome. Such claims may need to be further defined in terms of modifications that contribute towards an improved function.

Mechanical And Electrical

The trend for mechanical and electrical examination remains relatively consistent, with Australian examiners continuing to primarily draw upon foreign examination results when accessible. In cases where foreign examination results are unavailable, examiners conduct independent searches, the results of which are generally of a high standard.

Support objections seem to have increased in frequency compared to previous years, with examiners typically asserting that the claim scope extends beyond the disclosure of the specification.

Software

The frequency of non-patentable subject matter objections being raised against software inventions also seems to have increased. The most viable option for overcoming this type of objection is presenting the technical features of the invention. However, examiners increasingly respond by asserting that the technical features are not sufficiently described in the specification (ie, an enablement objection is raised).

APPEALING OFFICE DECISIONS

The avenues available to seek a judicial appeal or administrative review of a decision of the Commissioner of Patents vary depending on the nature of the decision that is sought to be appealed, and are specified in the Patents Act 1990 (Cth).

Appeals To The Federal Court Of Australia

Decisions relating to acceptance or opposition to the grant of an accepted standard patent application, and the examination, re-examination or opposition of an innovation patent, are

appealed to the Federal Court of Australia (FCA). An innovation patent is a 'second tier' form of patent protection with a shorter (eight year) term and with a lower threshold of patentability. They still exist in Australia but are currently being phased out.

Typically, the deadline to file an appeal to the FCA is 21 days from the date of the decision. As this deadline can be difficult to extend, it is important to treat it as final and to act promptly (including to seek appropriate legal advice) before its expiration.

An appeal to the FCA from a decision of the Commissioner is conducted as a hearing de novo. This means that the FCA 'stands in the shoes' of the Commissioner and makes the decision afresh without being limited to the arguments, grounds or evidence that were before the Commissioner. Accordingly, the parties can generally set out additional grounds and particulars in the notice of appeal and file new evidence.[8]

Reviews To The Administrative Appeals Tribunal Or The FCA

Decisions such as in patent eligibility disputes and certain extensions of time requests are reviewed by the Administrative Appeals Tribunal (AAT).

Where the Patents Act does not specify a right of appeal or review, generally the only avenue is judicial review under the Administrative Decisions (Judicial Review) Act (ADJR Act).

Typically, the deadline to apply for a review to the AAT, or the FCA under the ADJR Act, is 28 days from the date of the decision, and a similar order of steps follows as that of appeals before the FCA.

OPPOSITIONS AND RE-EXAMINATION

Oppositions and requests for re-examinations are commenced before the APO.

Oppositions

Oppositions are available in relation to both standard patents (pre-grant) and innovation patents (post-certification). In the case of a standard patent, as the opposition procedure is available pre-grant, it can prevent the application ever being granted.

However, innovation patents are subject to a different registration process where they are initially granted without examination (provided formalities are complied with) and certified (if examination is requested) so that they can be enforced. Oppositions can only be commenced after certification is completed.[9]

As deadlines during opposition proceedings can be difficult to extend, it is important to treat these deadlines as final and to act promptly.

Re-examination

The patentee or any other person can request re-examination any time after acceptance of a standard patent, or certification of an innovation patent. The Commissioner is not obliged to carry out a re-examination of a standard patent before grant and may take the view that it is appropriate that an opposition be brought in such circumstances.

In some circumstances, the Commissioner may decide (at their discretion) to re-examine a patent without a request for re-examination. This is typically in circumstances where additional prior art comes to the attention of the APO, which was not previously considered during examination, or where grounds are raised in an opposition that are subsequently withdrawn.

Unlike oppositions, once a third-party requests re-examination, they play no subsequent role in the re-examination process, which continues between the APO and the patentee.[10]

During re-examination, an examination report will issue that outlines the examiner's findings. In the case of an adverse report, the patentee will be given the opportunity to respond with written submissions or amendments within a set deadline. If the patentee cannot resolve issues encountered during re-examination, the Commissioner will typically set the matter for a hearing prior to revoking the patent either wholly or in so far as it relates to a particular claim.

For completeness, we note that once any proceedings concerning a patent are commenced before the FCA, any proceedings before the APO (including re-examination) cannot proceed until the FCA proceedings are finalised. This creates strategic considerations for both patentees and challengers in determining the best forum for a patent challenge.

INVALIDATION AND INTER PARTES REVIEW

Revocation (ie, invalidation) proceedings are commenced before the FCA. While typically such proceedings are commenced in response to infringement proceedings, they can be commenced pre-emptively with the FCA.[11]

Revocation proceedings are typically heard and determined at first instance by a single judge. An appeal is available as of right to the Full Court of the FCA, typically consisting of three judges. There are no jury trials in Australia for patent cases.

There is no exact equivalence in Australia of the inter partes review procedure available before the US Patent and Trademark Office. The pre-grant procedure in Australia in relation to standard patent applications is the closest that is available.

PATENT TERM EXTENSIONS

The Act provides patent term extensions (PTE) for patents disclosing and claiming a pharmaceutical substance per se, or a pharmaceutical substance produced by a process that involves the use of recombinant DNA technology that is registered on the Australian Register of Therapeutic Goods (ARTG).[12] While method of treatment and Swiss style claims do not render a patent eligible for a PTE, extensions have been granted on slow release formulations, transdermal patches, unit doses and nanoparticulates, in contrast to the position in other jurisdictions such as Europe.

The term of a patent cannot be extended more than once;[13] however, the term of multiple patents can be extended on the basis of a single registration of a pharmaceutical product.

The date of first regulatory approval is of particular importance for eligibility of a PTE as the Act provides that this date is utilised to determine whether the patent is eligible to be extended,[14] the date by which the PTE request must be filed,[15] and the length of extension permitted.[16]

Determining the date of first regulatory approval when more than one product falls within the scope of the claims has been contentious in recent years. The Full Federal Court of Australia clarified that a PTE should be based on the earliest Australian regulatory approval date of any pharmaceutical substance that is disclosed and claimed in the patent, irrespective of whether the substance was developed by the patentee or a competitor.[17] Accordingly,

owners of pharmaceutical patents or applications should monitor competitor activities within Australia.

For patent applications covering multiple potentially registrable products, it is prudent to file divisional applications such that each potentially registrable product is covered by a separate patent. This approach facilitates independent PTEs based on the respective regulatory approval dates for each product.

PENDENCY LEVELS

A record number of standard patents were filed in 2021, and this decreased slightly in 2022, when 32,264 standard Australian patent applications were filed and 16,407 patents were granted.[18] In recent years, new patent filings in healthcare fields have dominated patent filings compared with other fields, with 13.8 per cent, 12.5 per cent and 10.3 per cent of new filings occurring in pharmaceutical, medical technology and biotechnology fields, respectively.[19]

The time between requesting examination and receipt of an examination report is presently stretching well beyond the 12 months targeted by IP Australia in some fields. This is particularly true for applications in pharmaceutical and related healthcare technologies.[20]

IP Australia provides timeframes for examination for each subject area as follows:[21]

Subject area	Examination time
CHEM 1 – Biotechnology	19 months
CHEM 2 – Chemical compounds	19 months
CHEM 3 – Biotherapeutics	26 months
CHEM 4 – Polymers and applied chemistry	12 months
CHEM 5 – Pharmaceuticals	16 months
ELEC 1 – Physics	10 months
ELEC 2 – Electronics and communications	8 months
ELEC 3 – Computing	9 months
ELEC 4 – Data processing and measurements	11 months
MECH 1 – Mechanical engineering	14 months
MECH 2 – Construction and mining	14 months
MECH 3 – Process engineering	11 months
MECH 4 – Medical devices	12 months
MECH 5 – Packaging and appliances	14 months

Options to reduce the wait time for issuance of examination include requesting examination early (eg, upon entering the Australian national phase or filing an Australian standard patent application) and requesting expedited examination as detailed below.[22]

An examination report can be expected four to eight weeks following the acceptance of a request to expedite examination. Once an examination report issues, the application must be accepted within 12 months.

AUSTRALIAN PROSECUTION POINTERS

Divisional Applications Can Be Daisy-chained

Under Australian law, successive divisional applications can be 'daisy-chained' to maintain pendency of patent claims throughout the 20-year term of an original parent patent. Maintaining the pendency of patent claims via a divisional application offers numerous strategic advantages from a commercial and litigation standpoint.

Expired Innovation Patents

The innovation patent was phased out on 25 August 2021 and all innovation patents will have expired by 26 August 2029; however, even expired and unexamined innovation patents remain a risk for potential infringers. Innovation patents were granted without examination but are not enforceable until examined and certified.

The APO recently examined two innovation patents after they had expired. Under Australian law, there is no requirement for an innovation patent to be alive when examined or certified. Therefore, a dead innovation patent could be retrospectively certified and enforced, although there is an overriding statute of limitations for patent infringement of six years.

Computer-related Inventions

Currently, Australia's view on the patentability of computer-implemented inventions is not in line with the United States and Europe. For the reasons discussed above, it is becoming increasingly difficult in Australia to patent a computer-related invention as there are widespread differences in opinions about the circumstances and requirements a computer-implemented invention must satisfy in order to be deemed patentable under Australian law.

It had been hoped that the highly anticipated decision of Aristocrat Technologies Australia Pty Ltd v Commissioner of Patents [2022] HCA 29 would clarify the requirements for finding a manner of manufacture for a computer-implemented invention. However, the High Court handed down an evenly split decision, leaving the door open to further consideration of the patentability of computer-implemented inventions in the future.

Expedited Examination Options

Australia is a member of the Global Patent Prosecution Highway programme.[23] There is also a separate Patent Prosecution Highway pilot programme between IP Australia and the European Patent Office.[24]

Alternatively, it is possible to request expedited examination for commercial or legal (eg, infringement) reasons, if the applicant is a small to medium sized enterprise, or if the invention is in the field of 'green technology', without the use of the Patent Prosecution Highway.

Requesting expedited examination offers a number of advantages over using the Patent Prosecution Highway. As there is no requirement for formal claim comparison charts or preliminary amendments to conform claims to a corresponding patent in another

jurisdiction, the costs of requesting expedited examination may be less. Further, there is no need to have a prior corresponding allowed or granted patent in an overseas jurisdiction. Expedited examination also takes place at the same pace as with the Patent Prosecution Highway programme and a rapid turnaround of an examination report can accordingly be expected.

Artificial Intelligence Inventorship

The High Court of Australia recently rejected an appeal that challenged a decision in-Commissioner of Patents v Thaler [2022] FCAFC 62. In the Thaler case, an AI system referred to as DABUS was alleged to be an inventor. However, it was decided an 'inventor' in an application for a patent must be a natural person.

In view of that decision, the current state of Australian law is that an inventor on a patent application cannot be an AI system.

Endnotes

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China: CNIPA Reforms Set to Make the Country an Attractive Venue to Innovate

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Summary

IN SUMMARY

This article summarises the latest developments in the Chinese patent industry, including the reform of the CNIPA, patent filing statistics, litigation and awarded damages, the growth of Chinese patent agencies, the latest legal changes including the amended patent law, and Hauge international design applications. The shortened examination period and its benefits and drawbacks are also discussed. Some reminders for joint R&D activities are proposed. These developments make China more attractive for innovation and make Chinese patents more valuable.

DISCUSSION POINTS

- Reform of the CNIPA
- Statistics of patent filing, litigation and damages
- Growing number of Chinese patent agencies
- Amended Chinese patent law and its Interim Measures
- China has joined the Hague System
- Shortened examination period

REFERENCED IN THIS ARTICLE

- China National Intellectual Property Administration
- Chinese Patent Law (revised and effective as of 1 June 2021)
- Announcement by the CNIPA on the Interim Measures for Examination related to the Implementation of the Revised Patent Law (Announcement No. 510)
- Interim Measures of Related Provisions after China's Accession to the Hague Agreement Concerning the International Registration of Industrial Designs (Announcement No. 511)
- National Intellectual Property Agency Industry Development Status (2022)

Although China suffered due to the covid-19 pandemic over the past three years and experienced difficulties caused by strict countermeasures stemming from the pandemic, global economic depression, global inflation and the Russia-Ukraine conflict, the intellectual property industry in China has demonstrated robustness and resilience. Various patent developments in the past year mean that China is more attractive for innovation and Chinese patents are more valuable. Most notable developments are summarised below.

REFORM OF THE CNIPA

The Chinese Patent Office was originally established in 1980. It was then renamed as the State Intellectual Property Office (SIPO) and became an entity directly under the State Council of China in 1998, mainly responsible for patent administration and coordinating intellectual property matters with other countries.

In 2018, following another institutional reform of the State Council, SIPO absorbed the Chinese Trademark Office and was renamed as the China National Intellectual Property Administration (CNIPA), and also became an entity under the State Administration for Market Regulation. The CNIPA realised the centralised and unified management of patents, trademarks and geographical indications, as well as the comprehensive administrative enforcement of trademarks and patents, which is an important method of enforcement in addition to judicial enforcement via the court system.

According to the latest institutional reform of the State Council on 20 March 2023, the CNIPA once again became an entity directly under the State Council, marking another big step in Chinese intellectual property development. The CNIPA is responsible for improving the creation, application, protection, management and service of intellectual property, including patents, trademarks, geographical indications and layout designs of integrated circuits. At the same time, the duty of carrying out administrative enforcement for trademarks and patents will be undertaken by the State Administration for Market Regulation, but will be guided by the CNIPA.[1]

According to the current reform, we can expect that the CNIPA and the State Administration for Market Regulation may play better roles in the future. The CNIPA may focus on improving the management of patents and trademarks to improve the quality of patents and trademarks, while the State Administration for Market Regulation, with its 600,000 enforcement personnel, may try to provide stronger guarantees for IP protection.

INCREASING GROWTH OF HIGH-QUALITY PATENTS

China's patent system provides protection for three types of patents: invention patents, which correspond to standard patents with a 20-year term; utility models, which protect only the improvement of the structure and configuration of the product and have a 10-year term; and design patents, which provide 15 years' protection for applications filed on or after 1 June 2021 (old design applications and design patents filed before 1 June 2021 still have 10 years' protection).

As shown by Table 1, even though during the pandemic the global economy was under high pressure, innovations in China and other countries were still growing. The CNIPA in particular, as a leading patent filing and granting office and part of IP5 (the CNIPA, USPTO, EPO, JPO and KIPO), maintained a stable growth in the number of granted invention patents, from both Chinese applicants and foreign applicants from 2019 to 2022. We currently only have the amount for the first six months of 2023, but we can expect the granted patents amount will exceed that of 2022.

China has a huge number of granted utility models, accounting for almost 97 per cent of global utility model filings. This huge number has received lots of complaints in recent years since a large amount of these obviously lack novelty, which increases the burden on enterprises and society to challenge their validity. Since 2021, the CNIPA has tried to use an AI-based search system to do an automatic prior art search and sort out those utility models that lack novelty. As a further, upgraded measure, the CNIPA is considering carrying out a non-obvious inventive step examination against utility models, which is expected to be implemented later this year or early next year. Good results have been shown from these steps – the granted number of utility models has decreased significantly in 2022 and the same trend would likely continue in 2023. However, the value of a Chinese utility model should not be underestimated. In a patent infringement litigation, Zhuhai Gree

Electric Appliances sued Ningbo Aux Air-Conditioning Co, LTD for infringing a utility model ZL200820047012.X. Zhuhai Gree Electric Appliances was awarded 40,000,000 yuan (about US$5,550,000) as damages by Guangzhou Intellectual Property Court, the first instance court, and this was upheld by Guangdong Higher People's Court, the second instance court.[2]

As with utility models, the CNIPA also now holds a stricter preliminary examination for designs and sorted out a good number of design applications that were the same as or very similar to prior designs. This is one reason why the number of granted designs dropped in 2022. Another reason for the lower number of granted design patents might be the delayed examination for certain design applications, especially for those applications involved in partial designs. Since the Implementing Regulations of the Patent Law and the Guidelines on Examination of Patents (1 February 2010) have not yet been revised, the examination of partial designs has been suspended for a while. Likewise, the CNIPA is also considering carrying out an obvious distinctiveness examination on designs in the near future.

Since 2021, the CNIPA has put lots of energy into cracking down on abnormal patent applications that are not for the purpose of protecting innovation. In 2022, about 955,000 patent applications were categorised as abnormal applications. This is also a reason why the number of patent filings and granted patents dropped in 2022.

	2019	2020	2021[[3]]	2022[[4]]	2023H1 [[5]]
Invention patents					
Chinese applicants	360,919	440,691	585,910	695,591	382,774
Foreign applicants	91,885	89,436	110,036	102,756	49,858
Utility models					
Chinese applicants	1,574,205	2,368,651	3,112,795	2,796,049	1,101,424
Foreign applicants	8,069	8,572	7,195	8,106	2,799
Designs					
Chinese applicants	539,282	711,559	768,460	709,563	339,194
Foreign applicants	17,247	20,359	17,061	11,344	4,806

SURGE OF PATENT AGENCIES IN CHINA

According to the 'Development Status of the National Intellectual Property Agency Industry (2022)' issued by the CNIPA in May 2023,[6] the number of patent agencies kept consistently rapid growth in the past decade, as shown in Chart 1. In 2022, 645 new patent agencies were established and the total number of patent agencies in China (except agencies located in Taiwan, Hong Kong and Macau) reached 4,520. Moreover, in 2022 the number of registered patent attorneys reached 31,347, and 63,311 people passed the Chinese patent attorney qualification examination.

Among the 4,520 patent agencies, there are only 397 agencies that have been established for more than 20 years, as shown in Chart 2, and there are only 46 agencies that have more than 51 patent attorneys, as shown in Chart 3.

On one hand, the surge in patent agencies corresponds well to the increase in patent filings in China. On the other hand, those large numbers of newly established small agencies may face a severe challenge of survival due to the fierce quality and price competition in the Chinese market.

In 2022, the CNIPA continued to push forward the 'Blue Sky Initiative', aiming to crack down on the illegal behaviour and misconducts of patent agencies. 1,489 agencies were interviewed, out of which 923 were ordered to rectify and 238 were punished. In recent years, administrative regulation has become an important measure to reduce low quality or abnormal patent applications, and is a strong guarantee for promoting the healthy development of the Chinese IP industry that will benefit not only China but also the world. In the current circumstances, high-quality patent attorneys and high-quality agencies are still in short supply.

Chart 1: Number Of Patent Agencies

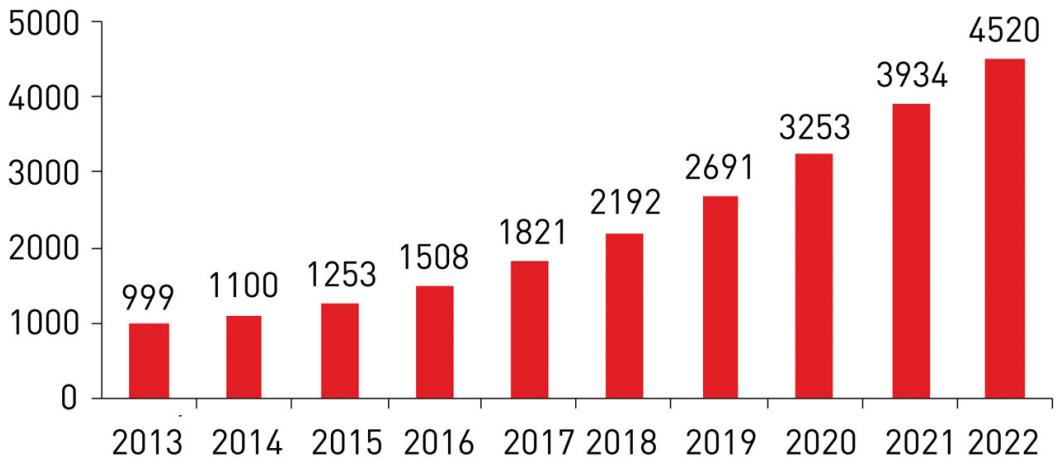


Chart 2: Years Of Establishment Of Patent Agencies

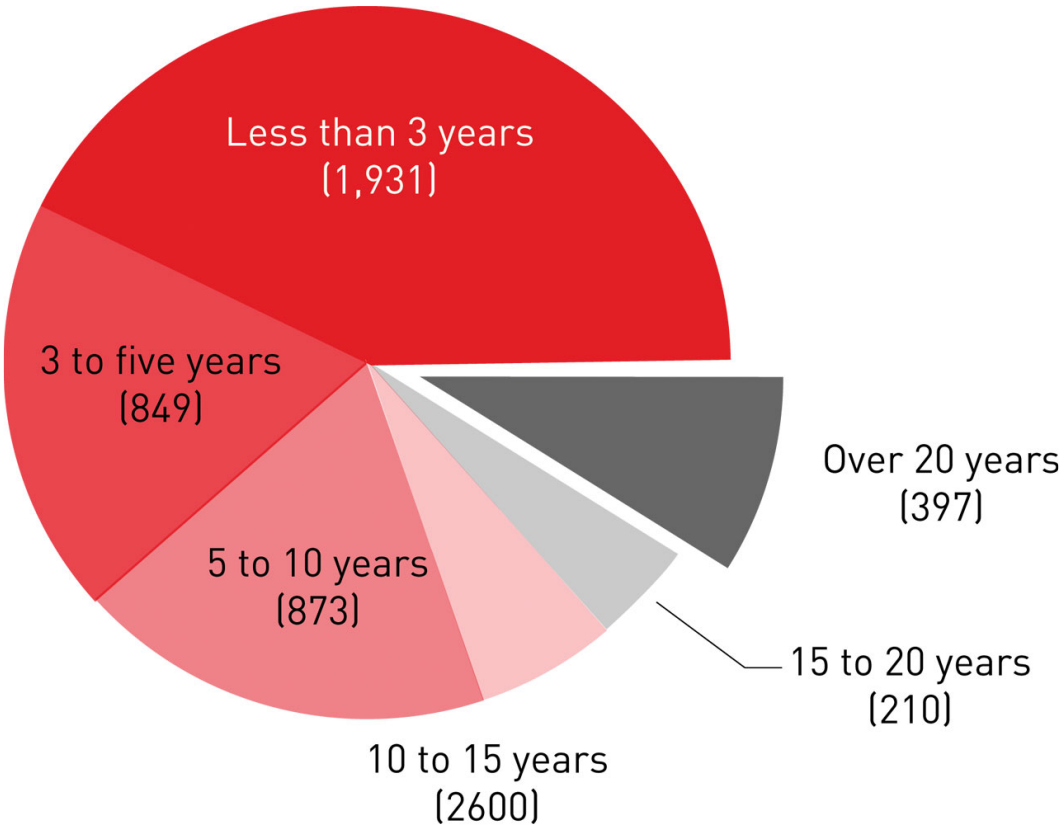
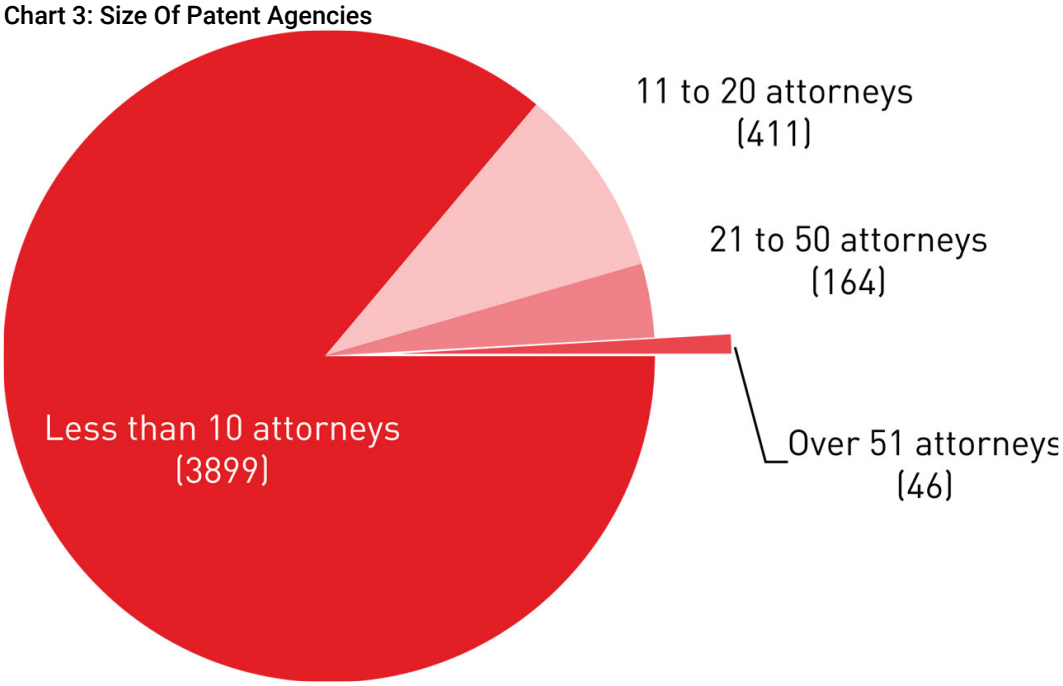


Chart 3: Size Of Patent Agencies



AMENDED CHINESE PATENT LAW AND ITS INTERIM MEASURES

The fourth amendments to the Chinese Patent Law came into force as of 1 June 2021.[7] These amendments mainly:

1. introduced punitive damage for serious intentional patent infringement, which may be up to five times the amount determined by actual losses suffered by the patentee, or benefits obtained by the infringer or multiple of the licence fees;

2. increased the statutory compensation from previously 10,000 yuan (about US$1,400) to 1 million yuan (about US$140,000), to currently 30,000 yuan (about US$4,100) to 5 million yuan (about US$700,000);
3. improved burden of proof, for which the infringer may be ordered to provide the account books and materials relevant to the infringement, or will have to bear the adverse consequences;
4. introduced partial designs, extended the protection term of designs from 10 years to 15 years and made it possible for designs to claim domestic priority;
5. introduced patent term adjustment to compensate for unreasonable delays caused by the CNIPA;
6. introduced patent term extension to compensate for a delay of administrative approval for a new drug;
7. introduced a drug patent linkage system to solve the potential dispute between a branded drug company and generic drug company in the early stages of administrative approval for a new drug;
8. further improved the patent administrative protection system;
9. introduced a good faith principle to stop bad faith patent applications and abuse of patent rights;
10. revised the service invention mechanism, according to which inventions made by a person in the execution of tasks of the entity employing the person or made mainly by taking advantage of the entity's material and technical conditions, will be regarded as service inventions;
11. introduced open licence system, which allows patentees to easily licence their patent to any potential person or entity;
12. introduced one circumstance in which an applicant may enjoy a six-month grace period for novelty if the applicant disclosed their invention in the public interest; and
13. revised the rules for requesting patent evaluation reports for utility models and designs, which are necessary for judicial or administrative enforcement – according to the revised rules, the alleged infringer may request for the CNIPA to issue such a patent evaluation report.

Unfortunately, the Implementing Regulations of the Patent Law and the Guidelines on Examination of Patents (1 February 2010) are still in the process of revision and approval, and have not been officially released yet. There is no concern for the court system to carry out the above points (1) to (3); these points were actually carried out by courts before the revision of the Patent Law. For the other points, which relate to administrative procedures carried out by the CNIPA, more detailed rules and guidelines are still necessary.

In order to guarantee the smooth practice of the amended Patent Law, and especially to fulfil the need for examination of partial designs and domestic priority of designs, the CNIPA made Announcement No. 510[8] stating some Interim Measures for handling examinations on 4 January 2023, which were put into force on 11 January 2023. There are two important points in this Announcement that should be noted:

•

when applying for a partial design, the applicant shall submit the drawings of the whole product, and the part to be protected should be indicated by a combination of dotted lines and solid lines or other methods; and

- a design application may claim priority from previously filed Chinese design applications, invention patents or utility models, if the product to be protected by the design was shown in the drawings of an invention patent or utility model.

CHINA HAS JOINED THE HAGUE SYSTEM

China has joined the Hague System, becoming the 94th contracting member on 5 February 2022. This means non-Chinese residents may have another option to get design protection in China from 5 May 2022.

The World Intellectual Property Organization (WIPO) Hague System is an international design system that provides a unique international mechanism for securing and managing design rights simultaneously in more than 90 countries through one application, in one language with one set of fees. However, since China has made a couple of unique declarations to be in line with the Chinese Patent Law, special attention must be made when filing an international design via the WIPO Hague System. WIPO's website[9] and the CNIPA's website both list these declarations and interim measures for the Hague Agreement.[10]

Based on recent refusals issued by the CNIPA with respect to international designs, we would like to remind readers of the following points, which might be overlooked but are irreparable:

- The requirements for drawings are different from European practice, where only formal requirements need to be met. According to Chinese requirements, for a three-dimensional design, it would be better to provide six orthographic views and one perspective view of the product, unless some of the orthographic views are symmetric or are not seen in use. Supplementing new drawings after the filing is not allowed, and in most situations like this, there is no way to save the case.
- The unity requirement is different from European practice, where one community design application may include several designs if these designs belong to the same class of the Locarno Classification. According to Chinese requirements, one application may only contain one design, unless several, up to 10, designs are similar designs for the same product, or several designs are incorporated in a set of products that are customarily sold or used at the same time. When the international application does not meet the Chinese unity requirement, the applicant may request to split multiple designs into divisional applications.
- Where priority is claimed in an international application, the CNIPA requires the submission of a priority document – failing to submit this will result in loss of the priority, which is not remediable. The priority document should be submitted when filing the international application via WIPO or submitted directly to the CNIPA within three months from the date of publication of the international registration in the International Designs Bulletin.

Considering the very different practice of China and the high risk of loss of the rights due to inappropriate submission, we strongly recommend that the applicant carefully review all of the guidelines provided by WIPO's website, or consult Chinese patent attorneys before formally filing an international application.

SHORTENED EXAMINATION PERIOD

The CNIPA continues to improve the examination quality and efficiency of patents and aims to reduce the examination period for invention patents to 16 months (counted from the date when the invention patent enters the substantive examination stage) within the year of 2023.[11]

This will be good news for those applicants who want a quick grant. For those applicants who want a slow grant, delayed examination may be used, which may delay the examination by one year, two years or three years. It should be noted that according to current practice, delayed examination cannot be withdrawn in advance once requested. Therefore, the applicant needs to plan the examination well in advance.

With the shortened examination period, we have seen an obvious trend that for those patent applications claiming foreign priority, the cases to be granted after the first office action or even without any office action has increased significantly since 2022, from 27 per cent in 2018 up to 66 per cent in 2023. At the same time, the cases rejected after the first office action also increased from 0.8 per cent in 2018 to 24 per cent in 2023. These statistics are based on the applications filed by one of the Top 10 Chinese patent firms.

According to the current trend, applicants should be more careful when preparing the response and amendment for the first office action. Strong and convincing arguments or amendments responding to the first office action may mean that the application is granted quickly – otherwise the chance of rejection increases dramatically.

Of course, after a rejection, re-examination is still available for the applicant, but it will obviously increase the cost for the prosecution. According to the annual report of the CNIPA,-[12] in 2022, out of 63,000 re-examination requests, about half of them succeeded and the rest were upheld or withdrawn.

INCREASED JOINT R&D

China remains one of the most favourable places for R&D and manufacture, and an increasing amount of joint R&D involving China is occurring. Like the US, China also has the requirement for confidentiality examination or foreign filing licence (FFL), before the applicant may apply for a patent abroad. This should be well noted by the joint R&D entities, otherwise a patent application not meeting this requirement cannot be granted a patent in China and a wrongly granted patent may be invalidated because it failed to meet the FFL requirement.

More specifically, the FFL requirement in China is based on the place where the invention is made, not the nationality of the inventors. In other words, if the invention is made primarily in China, the applicant will have the following options to get the FFL:

- the applicant may file the patent application (in Chinese) firstly in China and get the FFL from the CNIPA before the applicant files the same patent abroad;
- the applicant needs to request the FFL separately, alongside at least the Chinese specification (claims are not necessary, but it would be better if the applicant also provided claims), and then the applicant may file the application outside of China after getting the FFL from the CNIPA;
- if at least one of the applicants is a Chinese entity, the applicant may file a Patent Corporation Treaty (PCT) international application (which can be in English or

Chinese) before the CNIPA, and the FFL requirement will be deemed to be fulfilled after the CNIPA issues Form 105; or

- if none of the applicants is a Chinese entity but at least one of inventors has Chinese nationality or resides in China, it is also possible to file a PCT international application before the CNIPA by indicating the Chinese inventor as the applicant for a certain contracting member and designating other company applicants as applicants for desired contracting members.

STABLE INCREASES IN PATENT INFRINGEMENT LITIGATION AND AWARDED DAMAGES

Patent enforcement activities are increasing in China, reflecting the improved protection of IP in China. According to 'Judicial Protection of Intellectual Property Rights in Chinese Courts (2022)', first instance patent infringement litigation in 2022 reached 38,970 cases, an increase of 23 per cent upon the previous year.

Based on the statistics with respect to awarded damages in patent litigations,[13] from 2012 to 2022, the median awarded damages for invention patents increased from 100,000 yuan to 200,000 yuan, while the average awarded damages increased from 220,000 yuan to 2.58 million yuan, with an especially rapid increase after 2020.

Consistently increasing litigations and awarded damages reflect, on one hand, the strong determination of the Chinese government to build a stronger IP protection system in China, and on the other hand, make China a more preferable place for patent disputes.

Liuping Song, Huawei's chief legal officer, and lots of other professionals believe that Chinese patents will become the most valuable patents in the world. As China is one of the biggest markets and one of the biggest places for manufacture, once your patent covers China, you may get protection not only in China but also abroad. This belief is in the process of coming true.

Five Key Need-to-knows

1. Stably increased patent grants, litigation and awarded damages, together with the further reform of the CNIPA, make China a preferable place for patent protection
2. Changes to design are significant in China, and cares should be taken regarding partial design, extended protection term and domestic priority claiming
3. China joined the Hague System, but applicants should be aware of the different requirements of the CNIPA, such as full representations of the product, unity requirement and time for submitting the priority document
4. The CNIPA shortened the examination period to 16 months in 2022 – a good percentage of applications are granted after the first office action or even without any office action, while also an increased percentage of applications are rejected after the first office action
5. A foreign filing licence (FFL) is crucial for inventions made in China before the application can be filed abroad, many options are provided in China to get the FFL

Endnotes

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India: High Court IP divisions' landmark decisions reflect a positively evolving prosecution landscape

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Summary

IN SUMMARY

This article provides an overview of patent prosecution under Indian patent law. In India, patent prosecution is regulated by the Patents Act 1970. The patent prosecution process includes various steps and procedures, from filing a patent application to obtaining a grant of a patent. The whole process can be complex and time-consuming, however, understanding the various steps involved and the requirements at each stage is essential to ensure a successful outcome.

DISCUSSION POINTS

- Types of patents granted in India
- Time and costs involved in getting a patent granted in India
- Types of patent applications that can be filed in India
- Examination trends and procedures that potential applicants need to know
- Procedures related to appeals against patent office decisions, oppositions and invalidations
- Recent developments in different prosecution aspects due to recent court decisions

REFERENCED IN THIS ARTICLE

- *Ferid Allani v Union of India*
- *Microsoft v Assistant Controller of Patents*
- *Boehringer v Controller of Patents*
- *Syngenta v Controller of Patents and Designs*
- *Nippon v Controller of Patents*
- *Allergan v Controller of Patents*
- *OpenTV v Controller of Patents*

TYPES OF PATENTS GRANTED IN INDIA

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. India does not have provisions for utility models (also known as petty patents).

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 Patents Act 1970, 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.

The following are not patentable under the Indian Patents Act 1970:

- inventions that go against natural laws;
- anything contrary to public order or morality or anything 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 per se;
- 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.

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 claim as a whole and not the form of the claim. If, in substance, the invention is technical and the invention achieves a 'technical effect', then the invention does not fall under excluded subject matter. Recently, in May

2023, while referring to Ferid Allani v Union of India,[1] the IP Division of the Delhi High Court affirmed in Microsoft v Assistant Controller of Patents[2] that if the subject matter is implemented on a general-purpose computer, but results in a technical effect that improves the computer system's functionality and effectiveness, the claimed invention cannot be rejected on non-patentability as a computer program per se. India's stand on CRIs is similar to 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 the '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 that relates to a process for the 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.

TIME AND COSTS INVOLVED IN GETTING A PATENT GRANTED IN INDIA

Following continuous efforts, the long backlog of patent applications pending for 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 the payment of an additional fee. Under expedited examination, a patent can be granted within a year.

For official fee calculation purposes, applicants are either: natural persons, start-ups, small entities or educational institutions; or all others that do not fit into the first category (eg, large entities). The applicants that fall under the first category get an approximate 0 per cent 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 per cent 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 US$3,000 and US$4,000.

TYPES OF PATENT APPLICATIONS THAT CAN BE FILED IN INDIA

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

- fully and in detail describe the invention, 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 claims must relate to a single invention, or to a group of inventions linked by a single inventive concept; they must be clear and succinct; and they must be fairly based on the matter disclosed in the specification.

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
- patents of addition.

Only an ordinary application can be filed with a provisional specification. 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. As per settled jurisprudence, divisional applications cannot contain claims that were not claimed in the parent application. However, this stand has been recently referred to be considered afresh by a division bench of the Delhi High Court.

A patent of addition, which is similar 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 the Indian Patents Act 1970 for a continuation application to claim any unclaimed subject matter. In fact, what is not claimed is considered as disclaimed under the doctrine of disclaimer.

EXAMINATION TRENDS AND PROCEDURES THAT POTENTIAL APPLICANTS NEED TO KNOW

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.

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 parent application claims. The legal position related to the filing and maintainability of divisional applications in India is witnessing a rollercoaster ride as of now. In July 2022, the IP Division of the Delhi High Court in Boehringer v Controller of Patents[3] held that 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. The High Court also disallowed the duplication of the claims in the parent and divisional applications.

Recently, in July 2023, another judge of the IP Division in Syngenta v Controller of Patents and Designs[4] found that the aforesaid legal position appears to be not supported by the statutory provisions and therefore referred that question before the Chief Justice of the High Court, for constituting a two-judge Bench to examine the issues related to the filing of voluntary divisional applications and on the maintainability of claims in divisional that are carved out from the disclosure and not necessarily from claims of the parent application. It is hoped that the larger bench will clear all of the mist that shrouds the correct legal position on divisional applications under Indian patent laws.

Amendments

Provisions relating to claim amendments require that amended claims do not go beyond the scope of the original claims and are supported by the specification. That is why replacement or addition of claims is generally not permissible. In July 2022, the IP Division of the Delhi High Court in Nippon v Controller of Patents,[5] held that amendments to patent specifications or claims before the patent is granted must be construed more liberally than narrowly. Nothing new 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.

The aforesaid view was affirmed by the IP Division of the Delhi High Court in January 2023 in Allergan v Controller of Patents[6], where it was held that the exact scope of the claims have to be understood in light of the complete specification and that the claims and complete specification are to be read as a whole. Further, recently in May 2023, the IP Division of the Delhi High Court in OpenTV v Controller of Patents[7] held that reduction or narrowing down of a claim is permissible, but broadening, widening or expansion of a claim is not permissible. Thus, amendments are permissible for claims so long as the said amendments are within the scope of the originally filed claims.

PROCEDURES RELATED TO APPEALS AGAINST PATENT OFFICE DECISIONS, OPPOSITIONS AND INVALIDATIONS

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.

A 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 Patents Act 1970. Given recent court orders, anonymous oppositions ought to be discouraged by the IPO. After consideration of the maintainability of the 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. 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.

India does not have any provisions 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 Patents Act 1970, to accommodate third-party representations at various stages of the patent life cycle and at different forums.

A petition for the revocation of a patent can be filed by an interested person or by the 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 the disposal of such cases is provided under the Commercial Courts Act 2015, as intellectual property-related cases are considered commercial matters, and therefore, the 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 government under section 66 of the Patents Act 1970; and
- in cases relating to atomic energy on the directions of the government under section 65 of the Patents Act 1970.

After the abolishment of the erstwhile Intellectual Property Appellate Board (IPAB), which used to take care of revocation matters, the jurisdiction of these cases has been transferred to the high courts. The Delhi High Court (DHC), in February 2022, created the IP Division (IPD) for handling all intellectual property rights (IPR) matters, including those that are to be transferred from the IPAB. To date, more than 45 per cent of the patent appeals transferred from IPAB to the IPD have been disposed of.

Recently, in April 2023, the Madras High Court also created an Intellectual Property Division. Other high courts in the country are also expected to soon set up IP divisions.

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. 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.

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.

Under section 8(1) of the Patents 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 this information is also a ground for opposition or revocation. Under section 8(2) of the Patents 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.

Further, patentees and licensees are required to submit annual working statements indicating whether the patented invention has been worked or not. 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.

CONCLUSION

India has come a long way in the protection of patent rights in terms of progressive changes to adopt best practices and improve procedures. With the establishment of the dedicated IP Divisions in the high courts and the landmark decisions issued by them, the patent prosecution and enforcement landscape in India is set to further improve. The IPO has also taken significant steps to reduce the overall patent prosecution time in the country. It is hoped that India will soon be one of the top jurisdictions of choice for applicants to protect and commercialise their patents.

Endnotes

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Indonesia: Omnibus Law's Patent Regime Overhaul Raises Questions About Practical Implementation

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Am Badar & Am Badar

Summary

IN SUMMARY

As the world's fourth-most populous nation, the sleeping giant that is Indonesia continues its efforts to carve a place on the global stage. Intellectual property, especially patents, has emerged as one of the key areas that the government wants to improve upon. In this article, we will cover the newly enacted Omnibus Law in Indonesia from the perspective of patents. The focus will be on the changes it has brought to patent regulations in Indonesia, as well as the potential future of patent regulations in Indonesia.

DISCUSSION POINTS

- Background of the Omnibus Law in Indonesia
- Recent updates to patent regulations in Indonesia brought forward by the Omnibus Law
- The future of patent law in Indonesia

REFERENCED IN THIS ARTICLE

- The Ministry of Justice Indonesia
- The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement
- Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations
- Law of the Republic of Indonesia No. 13 of 2016, on Patents
- The Constitutional Court of Indonesia
- The People's Representative Council of Indonesia
- Decision No. 91/PUU-XVIII/2020
- Law No. 11 of 2020 on Job Creation
- Law No. 12 of 2011 on Legislation Making
- Law No. 6 of 2023 on Job Creation (the Omnibus Law 2023)
- The Ministry of Law and Human Rights

BACKGROUND

Patent laws in Indonesia have endured many significant changes throughout history, much like the nation. From being a Dutch colony that had to adapt its coloniser's patent laws, to becoming an independent nation that developed its own regulations (along with multiple revisions and changes), the evolution of Indonesia's patent laws has always reflected the nation's reality at the time. The series of deliberate revisions and adjustments to its patent laws were always the result of aligning with evolving economic, technological and societal priorities. Likewise, the most recent change to Indonesian patent regulations is a testament to a country that is consciously strengthening its role as a member of the international community, as well as encouraging its great potential for groundbreaking innovations.

In March of this year, Law No. 6 of 2023 on Job Creation (the Omnibus Law 2023) was officially enacted after enduring a period of significant controversy. The Law was intended to create jobs as well as raise both foreign and domestic investment; however, many of its articles were adamantly criticised by the public. A popular opinion deemed that the bill heavily favoured capitalists and investors, while ignoring the rights of or even being outright harmful to the working class. This is because the Law reduced severance pay, cut mandatory leave, allowed longer work hours and permitted the hiring of contract and part-time workers in place of full-time employees. Furthermore, the Law's articles concerning the environment were sharply criticised by observers. The aversion towards the Law was so intense that it led to numerous protests and demonstrations nationwide.

The Omnibus Law had a lengthy and difficult road to becoming legitimised as an applicable law. Before it was brought forward, its predecessor was Law No. 11 of 2020 on Job Creation, a legal product that was similarly met with widespread scrutiny from the general public, academics and various politicians alike. In 2021, the Constitutional Court issued Decision No. 91/PUU-XVIII/2020, which declared Law No. 11 of2020 to be unconstitutional. In a hearing read out by Constitutional Justice Suhartoyo, the Court ruled that the formulation of Law No. 11 Year 2020 did not follow standard lawmaking procedures and subsequently instructed the government and People's Representative to revise the Law within a two-year period.

A year later, on 24 May 2022, in yet another controversial chapter of this saga, the People's Representative Council passed the revisions to Law No. 12 of 2011 on Legislation Making. This was in response to the Constitutional Court's ruling, as Law No. 12 of 2011 previously did not allow the Omnibus Law. Some sceptical observers viewed this act as a mere shortcut to legitimise the Omnibus Law.

Ultimately, despite intense pressure and protest from much of the public, the new Omnibus Law 2023was brought forward as a replacement for the previous one and was passed by the People's Representative Council on 21 March 2023. It has been in effect since 31 March 2023.This enactment signifies a new era for a wide range of sectors in Indonesia, not excluding intellectual property, and specifically to Law No. 13 of 2016 on Patents, on which the Omnibus Law 2023 has brought several important revisions to a few of its articles.

RECENT DEVELOPMENTS

The nature of Indonesia's new Omnibus Law 2023 could be identified by its name. The word omnibus is derived from Latin, meaning 'for everything' or 'many'. In the legal realm, the Omnibus Law 2023 refers to a single regulation that tackles various sectors at different levels. Thus, as the name suggests, the Omnibus Law 2023 was enacted to make numerous changes to wide-ranging sectors, including intellectual property. In regard to patents, it made several revisions to Law No. 13 of 2016, as described below.

Article 3 of Law No. 13 of 2016 on Patents stipulates what type of invention would qualify as either a patent or a simple patent. Article 3, paragraph 2 of Law No. 13 of 2016 on Patents stipulates that simple patents are granted for new inventions, improvements to existing products or processes and inventions susceptible to industrial application. With the Omnibus Law 2023, a paragraph defining the 'improvements from an existing product or process' is given to the article. In the newly created article 3 paragraph 3 of Law No. 13 of 2016, what constitutes improvements from an existing product or process includes 'simple products, simple processes, and simple methods'.

The next change is a more significant one. Article 20 of Law No. 13 of 2016 stipulates that a patent holder is required to use the products or processes they have patented in Indonesia. This is further explained by manufacturing or usage, which must also encourage technology transfer, investment absorption or the creation of jobs. In the Omnibus Law 2023, the requirement for patent holders is reduced only to either manufacturing, importing or licensing the patented products or products created from patented processes or methods. Meanwhile, all previously enacted social-based caveats were abolished. This change is highly criticised by some observers, who believe that article 20 covers an essential and commonly enforced principle called 'local working', or the compensation requested by the state for the patent recipient to implement their invention in the country that granted the patent. Furthermore, the abolishment of the requirement for technology transfer was also met with criticism.

Regardless, in the original drafts for the Omnibus Law 2023 bill, the Indonesian government detailed seven reasons why article 20 of Law No. 13 of 2016 needed to be revised. Those reasons, according to the draft, are as follows:

- the need for flexibility in regard to manufacturing products related to patents and technology transfer;
- article 20 is deemed discriminative, and thus incompatible with or a violation of article 27[1] of the TRIPS Agreement, which has been ratified with Law No. 7 of 1994 on Agreement Establishing the World Trade Organization;
- a violation of article 20 could result in the cancellation of a patent;
- the stipulations of article 20 could not be applied to any types of technology due to concerns related to costs, human resources, mastery of technology, etc;
- the requirement for technology transfer decreases investment opportunities;
- difficulty to practice; and
- transfer of technology is difficult to perform in Indonesia due to difficulties in acquiring resources.

The changes in article 20 affected other articles as well. Article 82 of Law No. 13 of 2016 stipulates the qualifications for a compulsory licence. Paragraph 1 of said law stipulates that a compulsory licence could be issued if a patent holder has not fulfilled their obligation to make products or use the process in Indonesia as referred to in article 19, paragraph 1, within a period of 36 months after the granting of a patent. With the Omnibus Law 2023, the paragraph now refers to the newly revised article 20 instead of article 19.

Lastly, the Omnibus Law 2023 made several changes to stipulations regarding simple patents. Article 122, paragraph 2, of Law No. 13 of 2016 stipulates that a request for substantive examination on a simple patent may be submitted together with the filing of the simple patent application or not later than six months from the simple patent application filing date and subject to fees. The Omnibus Law 2023 alters this paragraph by removing 'not later than six months as from the simple patent application filing date'.

The Omnibus Law 2023 changed the time needed for publications of simple patents. Article 123, paragraph (1) of Law No. 13 of 2016 originally stipulated that publications of simple patent applications are carried out not later than seven days after three months from the filing date. Under the Omnibus Law, this time period is extended to 14 days. Moreover, a

paragraph is added concerning oppositions against patent applications. The newly added paragraph states that stipulations regarding patent application oppositions in article 49, paragraph (3) and paragraph (4) do not apply to simple patent applications. Paragraph (3) stipulates on the duration in which the Minister would communicate an objection or opinion, while paragraph (4) stipulates the filing and response to said opinion or objection and the required maximum duration.

According to the original stipulations of article 124, the Minister is required to decide whether to grant or refuse a simple patent application no later than 12 months from the filing date. Under the Omnibus Law 2023, this duration is now shortened to six months.

FUTURE

The Indonesian Omnibus Law 2023, a sweeping and comprehensive piece of legislation aimed at stimulating economic growth and attracting investment, is intended to bring significant changes to various sectors, including the patent field. These revisions hold the promise of fostering innovation, streamlining bureaucratic processes and aligning the Indonesian patent system with international standards. However, as of now, the influence of the Omnibus Law 2023 has not been keenly felt on practical level, primarily due to the recency of the amendments and the lack of necessary delegated legislations that would provide the practical framework for their implementation.

The effects of change, particularly in the legal realm, often take time to manifest. The revisions to Indonesian patent law introduced by the Omnibus Law 2023 are no exception. The transition from the old legal framework to the new one requires adjustments, not only in the legal processes but also for the individuals and organisations involved. Therefore, it is natural that the true macro level goal of these amendments has yet to be fully felt, and their influence will only become more pronounced as time goes on.

Furthermore, the absence of implementing legislations to support the changes stipulated in the Omnibus Law 2023 could create a gap between the intentions of the lawmakers and the practical application of the revised patent law. Implementing legislations are important for fleshing out the details and mechanisms through which the broader provisions of a law are implemented. This lack of specific guidelines can lead to confusion among patent applicants, inventors and legal practitioners, potentially inhibiting the anticipated benefits of the Law.

Moreover, the level of awareness and understanding of the changes among relevant stakeholders, such as inventors, businesses and legal professionals, also plays a role. It takes time for such information to disseminate, and for individuals to adjust their behaviours and strategies accordingly.

Nonetheless, there is optimism that the Indonesian government recognises the importance of bridging these gaps and ensuring the full realisation of the Omnibus Law's potential impact on patent law. The introduction of delegated legislations specifically tailored to the revised patent law could kick-start meaningful change. By elucidating the procedures and requirements, delegated legislations would reduce ambiguity and promote a more efficient and transparent system.

However, despite the significant changes given to the Indonesian patent ecosystem by the Omnibus Law 2023, there have been plans to introduce a new patent regulation altogether. Since 2019, the Indonesian government has been developing a new legal product that would replace the currently applicable Law No. 13 of 2016 on Patents. According to the Acting

Director General of Intellectual Property, Razilu, three main issues are the driving force behind these plans.

The first is to drive national innovation. The Directorate General of Intellectual Property (DGIP) cited a 2019 statistic, which revealed that in Indonesia, patent applications from domestic applicants are greatly outnumbered by applications from foreign applicants: 20 per cent are domestic and 80 per cent are foreign. The government has expressed the intent to increase the number of national patents directly registered with the DGIP, especially for simple patents by academicians and local manufacturers.

The second is to improve the quality of the current patent service system. Bambang Sagitanto, a legal analyst for the DGIP, has stated that the new patent legislation would look to revise certain administrative aspects concerning patent services, such as, among others, the process of substantive examinations and the changing of applicant data. Annual fees for patent holders will also be changed, as they are considered burdensome and require patent holders to pay through their representatives. Another issue is the receivables that cannot be collected as a result of the annual fee mechanism for patents that do not comply with the payment of fees.

The third reason is to ensure that Indonesian patent regulations comply with or are compatible with the stipulations of the TRIPS Agreement. This issue has been touched upon before with the Omnibus Law, as article 20 of Law No. 13 of 2016 was controversially revised due to the original stipulation being deemed incompatible with or in violation of article 27 of the TRIPS Agreement.

Furthermore, an academic draft discussing the proposed patent law outlined several aspects of the current Law No. 13 of 2016 on Patents that would be changed under the developing regulation. Aside from those already mentioned, the aspects are as follows:

- The definition of simple patent as stipulated in article 3 of the Law No. 13 of 2016 on Patents needs strengthening so that simple patents can have practical advantages.
- In article 4, paragraph D mentions 'rules and methods containing only computer programs' as inventions that are not patentable. Computer programs in this article should be further defined as programs that do not have character, technical effects or problem-solving qualities.
- Article 4, paragraph (F) No. 1 stipulates that inventions do not include new usage of existing products, while the next passage stipulates that new forms of existing compounds that do not generate significantly enhanced efficacy and contain different relevant known chemical structures also do not qualify as inventions. The draft mentions that these two stipulations were originally put in place to prevent patent evergreening; however, they could also stifle the economic growth of local industries because local industries and research are limited to original products. Also, the two stipulations are deemed to be dismissive of potential research.
- The grace period of the patent registry for inventions that have been announced.

In a significant step forward, Acting Director General Razilu has confirmed that the new patent law bill has been approved by both the People's Representative Council and the government, as represented by the Ministry of Law and Human Rights. Consequently, this bill has been integrated into the comprehensive national legislative package along with the

new Industrial Design Bill. With these strides, the near future could include the forthcoming enactment of a new patent law in Indonesia.

Given Indonesia's status on the global stage, this bill will definitively chart the technological and innovative trajectory of one of the world's biggest economies. Thus, an understanding of this pivotal juncture is essential. IP professionals, businesses and inventors are well-advised to monitor not only this bill in particular, but also the ever-developing landscape of Indonesia's patent realm.

Five Key Need-to-knows

1. In Indonesia, computer programs without character, technical effects or problem-solving qualities are not patentable. Otherwise, they are patentable
2. Methods of examination, treatment usage or surgery applied on humans or animals are not patentable
3. Essential biological processes for producing plants or animals are not patentable. However, applicants can claim patents of genes from plants, non-biological processes or microbiological processes of a plant or animal
4. As stipulated in article 22 of the Law on Patents, a patent is granted for a period of 20 years counted from the filing date and this is not extendable
5. For simple patents, 'inventive steps' are not required for patent eligibility and the protection period lasts for 10 years

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Endnotes

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Philippines: How to Ensure Patents are Granted and Pitfalls to Avoid

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Summary

IN SUMMARY

This article examines some selected issues in obtaining invention patents in the Philippines, and offers some guidance to practitioners and inventors in navigating avoidable hazards that could delay or result in the rejection of a patent application.

DISCUSSION POINTS

- Inventions eligible for patent protection, and eligibility issues
- Significant amendments to the implementing rules on inventions
- Issues affecting appeals
- Invalidation and inter partes reviews

REFERENCED IN THIS ARTICLE

- The Intellectual Property Code of the Philippines (Republic Act No. 8293)
- Revised Implementing Rules and Regulations for Patents, Utility Models, and Industrial Designs (Intellectual Property Office of the Philippines Memorandum Circular No. 2022-016)
- Food and Drug Administration Act 2009 (Republic Act No. 9711)
- Universally Accessible Cheaper and Quality Medicines Act 2008 (Republic Act No. 9502)
- Intellectual Property Office of the Philippines 'Manual for Patent Examination Procedure'
- Intellectual Property Office of the Philippines 'Examination Guidelines for Information and Communications Technology Patent Applications 2022'
- Intellectual Property Office of the Philippines 'Guidelines for Examination of Patent Applications in the Field of Biotechnology'
- Examination of Pharmaceutical Applications Involving Known Substances (QUAMA Guide)
- Patent Prosecution Highway
- Intellectual Property Office of the Philippines 2022 'Clarity Guidelines for Patent Applications'

The Philippines is a member of several international treaties involving patents, such as the Patent Cooperation Treaty (PCT), the Paris Convention for the Protection of Industrial Property and the TRIPS Agreement, which fixed the rights and obligations among its member countries, and established an international law of substantive minimum standards for national IP laws, as well as common procedural requirements to administer and maintain intellectual property rights for the purpose of worldwide harmonisation.

The Philippines also has bilateral agreements with the US Patent and Trademark Office, the European Patent Office (EPO), the Japan Patent Office, the Korean Intellectual Property

Office and member states of the Association of Southeast Asian Nations (ASEAN): the Global Patent Prosecution Highway (PPH), a work-sharing programme where applicants can request for the accelerated examination of their patent applications. Having a PPH, however, does not guarantee that the national IP office conducting the later examination will automatically allow and grant the application, since territorial patents apply. However, applications under the PPH are given priority, are free of charge and the usage of work products facilitates examination.

About 90 per cent of patent applications filed in the Philippines, as shown in the chart below,[1] come from foreign applicants, and 90 per cent of applications are done through the PCT, hence the need to be more familiar with the Philippine IP system for inventions.

INVENTIONS ELIGIBLE FOR PATENT PROTECTION

Section 21 of the Intellectual Property Code of the Philippines (the IP Code) defines a patentable invention as 'any technical solution of a problem in any field of human activity which is new, involves an inventive step, and is industrially applicable'. The statutory classes of patentable inventions are:[2]

- a product, such as a machine, a device, an article of manufacture, a composition of matter or a microorganism;
- a process, such as a method of use, a method of manufacturing, a non-biological process or a microbiological process;
- computer-related inventions; and
- an improvement of any of the foregoing.

The exceptions[3] are:

- discoveries, scientific theories and mathematical methods, and in the case of drugs and medicines, the mere discovery of a new form or new property of a known substance that does not result in the enhancement of the known efficacy of that substance, or the mere discovery of any new property or new use for a known substance, or the mere use of a known process unless such known process results in a new product that employs at least one new reactant;
- schemes, rules and methods of performing mental acts, playing games or doing business and programs for computers;
- methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body;
- plant varieties or animal breeds or essentially biological processes for the production of plants and animals, except micro-organisms and non-biological and microbiological processes;
- aesthetic creations; and
- anything which is contrary to public order or morality.

COMPUTER-RELATED INVENTIONS

For computer-related inventions (CII) and those in information and communications technology (ICT), the examination guidelines[4] require that these inventions must have

technical character to carry out the solution and achieve a technical effect.[5] These guidelines are similar to the EPO examination guidelines involving computer programs.

Second Medical Use

In assessing patent eligibility and inventive step, the doctrine of inherency is used to explain the meaning of 'mere discovery'. The patentability of a second or subsequent medical use of existing pharmaceutical products is allowed in the Philippines, and the QUAMA[6] provides that method of treatment claims may be amended to first medical use claims if a substance is known but its pharmacological properties are not disclosed in the prior art. Second medical uses are to be drafted in a Swiss-type claim format (eg, use of a substance X in the manufacture of a medicament for the treatment of disease Y).

2022 REVISED IMPLEMENTING RULES AND REGULATIONS

The amendments to the Implementing Rules and Regulations for Patents (Revised IRR 2022) took effect on 20 September 2022. Some of the key changes are:

- The first publication fee, claims fee in excess of 5 claims must now be paid in full upon filing, and failure to do so could result in the application being deemed a failed application that shall not be published and may have to be filed anew. In case of excess payment, it will be treated as donation to the Intellectual Property Office of the Philippines (IPOPHL).
- The mandatory appointment of a resident agent and representative for non-resident applicants, and the failure to submit within one month from notice shall deem the application to be withdrawn.
- The voluntary withdrawal of applications shall be under oath, and if done after the first publication, shall be published for opposition. If opposition is granted, the applicant can appeal to the Office of the Director General (ODG) of the IPOPHL. If the opposition is denied, the withdrawal is granted and the application is forfeited.

APPEALING OFFICE DECISIONS

The appeal process from an examiner's rejection of the patent application or claims involves at least four stages with decisions rendered at each stage, namely:

- appeal the decision of the examiner to the Director of the Bureau of Patents (BOP); and
- appeal the decision of the BOP Director to the ODG of the IPOPHL.

The decision or order of the Director reversing the refusal of the examiner shall be immediately final and executory. However, if the decision of the Director affirms the refusal of the examiner, the applicant can:

- appeal to the ODG;
- appeal the decision of the ODG to the Court of Appeals (CA); and
- appeal the CA decision to the Supreme Court (SC).

Failure To Comply With The Formality Requirements

The BOP is quite strict when it comes to deadlines and other procedural requirements, although occasionally it does relax its rules.

English Is Required

ParexGroup SA filed two national entry applications claiming priority over its French applications filed on 3 November 2016, but only the abstract and the text of the drawings had English translations. The examiner issued a notice of invalid national entry, since the patent applications were not filed in the English language as required by the Philippines Rules on PCT applications (PRo-PCT). ParexGroup appealed the denial claiming:

- substantial compliance of the PRo-PCT;
- that the description and claims were already available on the World Intellectual Property Organization (WIPO) website;
- that it should be given the chance to correct deficiencies in its patent applications; and
- that it had subsequently submitted copies of the description and claims in English.

The BOP Director denied the appeal. Dissatisfied, ParexGroup appealed[7] to the ODG, which likewise denied the appeal. The ODG stated that the 30-month period given to those seeking the national phase of the PCT is a very reasonable period to comply with the PRo-PCT, and more so since it allowed an extension for another month that ParexGroup did not use, and finally because the submission of the English translation was done only after notification by the examiner. The ODG further stated that it is the applicant's duty to look after its own interest, and just like in lawsuits, reglementary periods and time limits must be strictly followed as they are considered as 'indispensable interdictions against needless delays and for orderly discharge of patent examinations'.

Reinstating Lapsed Patents

The BOP Director denied Incyte's petition for the reinstatement of its patent 1-2010-502616 ('616) that lapsed for failure to file the 10th year annual fees, stating that the IP Code does not provide for reinstatement. Incyte appealed to the ODG[8], arguing that it was erroneous for the Director to construe the lack of a specific provision in the IP Code as a prohibition. The ODG granted the appeal, holding that the circumstances of the case merited liberality, as Incyte had been diligently paying its previous annuities and the failure to pay the 10th and 11th year annuities was due to an error committed by an employee of its US agent who failed to communicate Incyte's instructions to pay – and because Incyte exercised due diligence upon knowing of the error, immediately arranging for the payment of the 10th and up to the 12th annuity dues with surcharges. Further, at the time the annual fees were due, the Philippines was under a state of public health emergency due to covid-19.

No Philippine Agent, No Application

The Revised IRR 2022 imposed even stricter rules for obtaining filing dates, meeting deadlines and complying with procedures. There may be days when patent agents are not their usual alert selves and forget to remind their foreign clients to issue their power of attorney or appointment of a resident agent. The Revised IRR 2022 makes the submission of the appointment of a resident agent or representative for non-resident applicants mandatory and gives one month from notice to comply, otherwise, the application is deemed to be withdrawn.[9]

Late Filing Is A No-no

On 12 July 2018, the ODG dismissed the appeal of Takeda[10] and held that it can only claim the filing date of the parent application within four months from date of receipt of the restriction. This case stemmed from a divisional application filed by Takeda on 1 June 2004, claiming priority over its parent Application No. 53455 filed on 18 June 1996. The examiner denied the claim for priority, stating that the claims of Application No. 53455 were subjected to the restriction requirements issued on 2 July 2002, that the applicant had four months to file the divisional and such period had lapsed. Takeda argued that it had filed a voluntary divisional application, which the BOP rejected. The ODG, in dismissing the appeal, ruled that 'patents should be strictly construed and given only to those inventions that have significantly contributed to existing arts'.

Failure To Meet Substantive Requirements

To be patentable, an invention must meet three requirements: novelty, inventive step, and industrial applicability, and must not fall within the exclusions.

Non-patentable: Anything That Is Contrary To Public Order Or Morality

Application No. 1/2017/500733 for 'Cannabis Extracts and Methods of Preparing and Using the Same' with priority claims from US applications, which entered the Philippines on 20 April 2017, was issued a substantive examination report with mailing date of 5 February 2021 rejecting all amended Claims 1-28 for being drawn to a subject matter contrary to public order or morality. The claimed cannabinoid formulation, the method of its production from cannabis extract and its medical use constitute matters that are contrary to public order or morality,[11] because the cultivation and use of cannabis in the Philippines is illegal under the Comprehensive Dangerous Drugs Act 2002 (Republic Act No. 9165).

Non-patentable: Abstract Ideas, Theories Or Fundamental Concepts

In the national phase application 1/2019/501851[12] the examiner objected to Claims 1-10 as constituting mere abstract and non-technical model training methods and data similarity determining methods, which lack the support of an apparatus or device, and appear not to be tangibly embodied in a manner as to be executable through interaction between method and apparatus – and therefore not patentable under Rule 202 of the Revised IRR 2022. Applicants are encouraged to present arguments against every ground of refusal and to support these arguments. For the purpose of expediting adjudication, the claims were examined with the assumption that technical elements are involved when carrying out the claimed method as stated in the description and in so doing, the examiner found the claim for convention priority allowable, meeting the requirements of novelty, inventive step and industrial applicability.

OPPOSITIONS AND RE-EXAMINATION MATTERS

The Philippines has no opposition procedure against patent applications, except for voluntary withdrawal of the application as earlier discussed. However, the IPOPHL invites the public to submit their observations, under oath, within six months, either through electronic mail or separate notification on the IPOPHL website, following the publication of the patent application.[13] The affiant must indicate their personal details. All observations are forwarded to the applicant, who may respond to the observations. Copies of any observations filed, comments on them by the applicant and minutes of conferences form part of the file wrapper in the subject application. The observation and comments, as well as the discussion in

the conferences, shall be taken into consideration when examining the patent application. Upon request, the IPOPHL will notify the third party of the status or final disposition of the application.

INVALIDATION OR PETITION FOR CANCELLATION

The IP Code provides that any interested party may, upon payment of the required fee, petition to cancel the patent or any claim or parts of the claim, on any of the following grounds:[14]

- what is claimed as the invention is not patentable;
- the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by any person skilled in the art;
- the patent is contrary to public order or morality; or
- the patent includes matters outside the scope of the disclosure contained in the application as filed.

For documents executed outside the Philippines, such as the power of attorney and affidavits, the authentication or apostille of these documents must have been done before the filing of the case.[15] A single pleading for petition involving more than one registration is allowed, provided that it involves the same parties and each patent sought for cancellation constitutes one distinct case. The petitioner has to pay the applicable fees corresponding to each and every patent sought to be cancelled. For this purpose, the petitioner may also submit a single power of attorney or proof of authority of the signatory, including the verification and certification of non-forum shopping.[16]

A petition for cancellation may be raised as a defence or a counterclaim in an action for patent infringement, and the same formalities on authentication or apostille as regards non-resident defendants and respondents apply.

If the petition meets the filing requirements, a notice to answer shall be issued to the respondent, which is given 30 days to respond (and can be extended by 45 days). The same requirements on formalities apply. If the answer is filed on time or the defects are cured, the case is referred to alternative dispute resolution for mandatory mediation.[17] The IPOPHL has a memorandum of understanding with the WIPO that for cases primarily involving one or more parties domiciled outside the Philippines, the parties can request for WIPO mediation, and the IPOPHL fees shall apply.[18] If the parties are able to forge an agreement within or outside the mediation period, and submit the same to the IPOPHL, the case is dismissed based on the agreement, which is equivalent to a judgment on the merits. If not, the prosecution of the case continues, the parties are required to submit their position papers, and the Adjudication Officer issues the decision within 20 calendar days from the date the case is submitted for decision, with a 20-day extension allowed.[19]

Case Example

Invalidity Of Patent As Defence

Bristol Myers Squibb sued Innogen[20] for infringing its patent '228 by selling to the public certain low doses of Entecavir compositions covered by '228, under the brand name Entegard. Innogen, for its part, filed a petition for cancellation of '228 for lack of novelty and inventive step, claiming that US Patent 5,206,544 (filed by practically the same owner

ER Squibb) was the first medical use as it already disclosed the active ingredient entecavir for treating Hepatitis B in humans, and because dosage forms were already within the knowledge of pharmacists (the persons skilled in the art). Innogen's cancellation case was dismissed, as the Biologics License Application (BLA) Director held that '228 is valid and stated that US Patent No. 5,206,544 does mention the substance entecavir and the illness Hepatitis B, but it cannot be prior art to '228 because no simple mathematical ratio and proportion of the amount of entecavir vis-à-vis the weight of the patient applying the alleged prior art is involved. Therefore, '228 pertains to an invention wherein a reduced dose of the active ingredient entecavir produces effective results without the undesirable side effects that can result from high dose required in US Patent No. 5,206,244.

According to the BLA Director:

> How to prepare a pharmaceutical with reduced dose of entecavir cannot be obvious to a pharmacist or any person skilled in this kind of field. At the most, the latter will only tweak the amount of entecavir depending on the body weight of the user as disclosed in U.S. Patent 5,206,244. Without the subject invention, pharmacists will not know that a smaller amount of entecavir, prepared as stated in the subject patent, will produce effective results.

It must also be noted that US Patent 5,206,244 was already considered by the examiner during the substantive examination of '228.

Five Key Need-to-knows

1. An invention must be novel, involve an inventive step and must be industrially applicable to be patentable
2. There are inventions that are not patentable
3. The Philippines adopts the 'first to file' rule, and a filing date is given only when all the requirements for a patent application are met
4. The Philippines has entered into bilateral agreements with USPTO, EPO, JPO, KIPO and the ASEAN countries, called the PPH, which expedites examination of patent applications
5. Be aware of deadlines to keep the patent application active

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Endnotes

1 Romero, Frederick (2023) 'The Philippines IP System', Beyond IP – Mastercourse. Back to section

2 Rule 201 of the Revised Implementing Rules and Regulations for Patents, Utility Models and Industrial Designs (2022). Back to section

3 Section 21, IP Code. Back to section

4 Intellectual Property Office of the Philippines 'Patent Examination Guidelines for Information Communications Technology and Computer Implemented Inventions' (2022). Back to section

5 ibid, section 3.4.1. Back to section

6 Revised Guidelines on the Examination of Pharmaceutical Applications Involving Known Substances (QUAMA Guide, Intellectual Property Office of the Philippines (January 2018). Back to section

7 ParexGroup SA vs Director of the Bureau of Patents, Appeal No. 01-2020-0007, Application Nos. 1-2019-550072, 1-2019-550073, Office of the Director General, IPOPHL. Back to section

8 Incyte Holdings Corporation v Director of Patents, Appeal No. 01-2021-0003, Office of the Director General 14 Feb 2023. Back to section

9 Rule 422, Revised IRR 2022. Back to section

10 Takeda Pharmaceutical Co, Ltd vs Director of Patents, Appeal No. 01-2013-0005, Application No. 1-2004-00210, 12 July 2018. Back to section

11 Section 22.6, IP Code. Back to section

12 Substantive examination report with mailing date of 11 July 2023 for application 1/2019/501851 for 'Model Training Method, Apparatus, and Device, and Data Similarity Determining Method Apparatus, and Device' with request for accelerated examination under the PPH Programme. Back to section

13 Rule 802, 803, Revised IRR 2022. Back to section

14 Section 61, IP Code; Section 1(a), Rule 3, Rules on Inter Partes Proceedings. Back to section

15 Section 7(c), Rule 2, Rules on Inter Partes Proceedings. Back to section

16 Section 7(d), Rule 2, Rules on Inter Partes Proceedings. Back to section

17 Section 11, Rule 2, Inter Partes Proceedings. Back to section

18 Rules of Procedure for IPO Mediation Proceedings. Back to section

19 Section 16, Rule 2, Inter Partes Proceedings. Back to section

20 Bristol Myers Squibb Holding Ireland vs Innogen Pharmaceuticals Inc, IPV No. 10-2013-00021, 18 December 2020. Back to section

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South Korea: IP Office's DABUS Nullification Highlights Stance Towards AI Inventors

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Summary

IN SUMMARY

This article delves into recent unfavourable decisions in South Korea from both the patent office and the administrative court, which pertain to a patent application listing an artificial intelligence, named 'DABUS', as an inventor. By furnishing a concise legal background, it investigates the prospect of a flexible legal interpretation. Furthermore, the article briefly addresses essential considerations for patent practitioners when filing a patent application involving an AI-generated invention.

DISCUSSION POINTS

- The Artificial Inventor Project
- Provisions and precedents related to inventorship in the Korean Patent Act
- KIPO's nullification decision based on articles 33(1) and 203(1)(iv) of the Korean Patent Act
- Seoul Administrative Court's decision additionally based on its alleged current level of AI technology and potential adverse repercussions on future innovations
- Necessity and potential for more flexible interpretation of inventorship
- Viable strategies for filing a patent application involving an AI-generated invention

REFERENCED IN THIS ARTICLE

- Articles 2(1), 33(1), 42(1) and 203(1) of the Korean Patent Act
- Supreme Court Case No. 2011Da67705, 67712 (27 December 2012)
- Intellectual Property High Court Case No. 2002Heo4811 (11 July 2003)
- Korean Intellectual Property Office 'White Paper on Artificial Intelligence (AI) and Intellectual Property' (March 2022)
- Seoul Administrative Court Case No. 2022GuHap8954 (30 June 2023)
- European Patent Office Legal Board of Appeal Case No. J 0008/ 20 - 3.1.01 (21 December 2021)

INVASION OF AI-GENERATED INVENTIONS INTO PATENT SYSTEM

Since a patent application was first filed with the European Patent Office (EPO) in 2018 for an invention generated by an artificial intelligence (AI) known as DABUS, patent offices and courts in many countries have rendered their own decisions on whether DABUS can be recognised as an inventor of the patent application. Although designating an inventor might appear to be a mere formality requirement for patent applications, it has sparked complex debates within international patent offices and courts. The core dilemma revolves around the eligibility of non-human entities, such as AI, to warrant protection within the established patent framework.

In South Korea, the Korean Intellectual Property Office (KIPO) and the Seoul Administrative Court have expressed their opinions regarding listing DABUS as the inventor in a patent

application. This article provides a brief overview of the Artificial Inventor Project associated with the DABUS application and outlines the determinations by KIPO and the Seoul Administrative Court. Furthermore, it offers pertinent factors for patent practitioners to take into account when filing applications for AI inventions in Korea.

ARTIFICIAL INVENTOR PROJECT

This global project is a collaborative endeavour unfolding across numerous countries, with primary objective of establishing that in cases where AI autonomously creates inventions without conventional human inventors, AI systems themselves can be recognised as inventors under the existing patent framework, thereby securing patent protection.[1]

Dr Stephen L Thaler stands at the forefront of this initiative, having developed a sentient artificial general intelligence named 'DABUS', which autonomously generated inventions (Fractal Container and Neural Flame).[2] Dr Thaler first filed an application designating DABUS as an inventor in Europe and subsequently filed a Patent Cooperation Treaty (PCT) application, then entered the national phase in various countries, including Korea.

The World Intellectual Property Organization (WIPO) officially received the PCT international application designating DABUS as the inventor. In 2020, the international application was published as WO 2020/079499 A1, listing 'DABUS, The invention was autonomously generated by an artificial intelligence' as the inventor. In addition, the Companies and Intellectual Property Commission (CIPC) of South Africa became the first patent office to grant a patent for the DABUS application.[3]

In contrast, courts in Australia and the United States issued conclusive decisions affirming that patent protection cannot be extended to applications that list AI as an inventor. The Legal Board of Appeal of the EPO also ruled that an inventor must be a natural person (a divisional application is now pending). Appeals against adverse decisions in relation to the DABUS applications are ongoing within various jurisdictions, including the UK, Germany and others.

KIPO AND THE SEOUL ADMINISTRATIVE COURT SAID 'NO' TO THE DABUS APPLICATION

Provisions And Precedents Related To Inventorship In The Korean Patent Act

Before discussing the progress of the DABUS application in South Korea, it is necessary to provide a brief overview of legal landscape and provisions in Korea concerning the concept of an 'inventor'. Unlike some jurisdictions, the Korean Patent Act does not explicitly define the term inventor. Instead, article 2(1) of the Korean Patent Act provides a definition for 'invention':

> Article 2 (Definition) The definitions of the terms used in this Act are as follows:
>
> 1. The term "invention" means the highly advanced creation of a technical idea utilizing the laws of nature.

Article 33(1) outlines the criteria for a person who is entitled to a patent:

> Article 33 (Persons Entitled to Patent) (1) A person who makes an invention or a successor thereof has a right to a patent under this Act:

Furthermore, articles 42(1) and 203(1) stipulate the manner of designating an inventor as part of the formality requirements for a patent application:

> Article 42 (Patent Applications) (1) A person who intends to obtain a patent shall file a patent application stating the following matters with the Commissioner of the Korean Intellectual Property Office:
>
> 1. The name and address of the applicant (if the applicant is a corporation, its corporation name and place of business);
>
> . . .
>
> 4. The name and address of the inventor
>
> Article 203 (Submission of Documents) (1) An applicant of an international patent application shall submit to the Commissioner of the Korean Intellectual Property Office, the following matters in writing within period for submitting documents in Korea.
>
> 1. The name and address of the applicant (if the applicant is a corporation, its corporation name and place of business);
>
> . . .
>
> 4. The name and address of the inventor

In the context of inventorship under South Korean case law, the Supreme Court has ruled that an inventor is required to 'make a substantial contribution to the creation activity of a technical concept' (Supreme Court Case No. 2011Da67705, 67712, issued on 27 December 2012). Furthermore, the Intellectual Property High Court (IPHC) has held that 'a person who makes an invention', as prescribed in article 33(1) of the Patent Act, exclusively pertains to 'a natural person who was actually engaged in the creation activity', thereby excluding a corporation from being deemed an inventor (IPHC Case No. 2002Heo4811, issued on 11 July 2003).

KIPO's Nullification Decision Regarding The DABUS Application

On 12 March 2020, Dr Thaler entered the international application into the Korean national phase, listing DABUS as the inventor and himself as the applicant. Upon formality examination, KIPO issued a notice on 18 February 2022, requesting him to replace the inventor with a natural person. In light of the unfulfilled request, KIPO issued a decision of nullification on 28 September 2022.

According to the KIPO's notice and nullification decision: article 33(1) of the Korean Patent Act stipulates that a right to obtain a patent is vested in a person who makes an invention or their successor, implying that an inventor pertains exclusively to a human being (ie, a natural person); and article 203(1)(iv) of the Korean Patent Act mandates the inclusion of the '(full) name and address of the inventor' in a patent application, and the '(full) name' refers to the name of a natural person, thereby confining inventorship to natural persons alone.

Meanwhile, apart from the examination of the DABUS application, KIPO took proactive measures by establishing and convening an advisory group composed of legal, technological and industrial experts, in August and September 2021. In March 2022, KIPO published the

'White Paper on Artificial Intelligence (AI) and Intellectual Property'. In this white paper, KIPO conveyed insights and perspectives of the Advisory Group as follows:

> Given the current state of AI technology, it is unlikely that AI will have the capability to autonomously make inventions without human intervention in the foreseeable future. Currently, AI functions solely as a tool for making inventions, and thus, is ineligible to be named as inventor. Even in cases of joint inventions involving both AI and humans, it is sufficient to designate only humans as inventors, thus, there is no legal gap within the framework of patent law. Additionally, it is unclear whether patent protection for AI inventions promotes advances in the field of AI, and there is no immediate need for South Korea to be ahead of other countries in legislating to allow inventors other than natural persons.[4]

Further, KIPO explored the legal requisite for inventorship, highlighting the necessity for AI to possess legal personality, a condition that could be realised through a revision to the Civil Act. Moreover, KIPO emphasised the imperative of ensuring international cohesion, especially considering that major foreign patent offices have yet to acknowledge AI inventors.[5] The nullification decision regarding the DABUS application can be perceived as an alignment with KIPO's stance that was outlined in the white paper.

Seoul Administrative Court's Dismissal Decision

On 20 December 2022, Dr Thaler filed a complaint against KIPO's nullification decision. After several exchanges of briefs between Dr Thaler and KIPO, as well as a hearing conducted on 12 May 2023, the Seoul Administrative Court rendered a decision (Case No. 2022GuHap89524) on 30 June 2023, dismissing Dr Thaler's complaint on the following basis:

> Article 33(1) of the Patent Act explicitly defines an inventor as a 'person,' i.e., a natural person, who makes an invention. In addition, Article 42(1)(iv) and Article 203(1)(iv) of the Patent Act require 'the (full) name and address' of an inventor to be indicated in a patent application. Even in view of the other sub-paragraphs in the same Articles that specify the inclusion of the (corporation) name and place of business for corporate applicants, it is evident that the term 'inventor' under the aforesaid provisions pertains exclusively to a natural person with a '(full) name' and an 'address.'
>
> At the current level of technology, there is no supporting evidence substantiating the emergence of strong AI, which refers to AI capable of autonomous decision-making and actions extending beyond human-developed algorithms or data. Similarly, DABUS does not appear to qualify as strong AI. Specifically, human involvement significantly contributed to DABUS's learning process. In the instant case, the sentences and graphs generated by DABUS were collected and restructured to comply with the patent specification format by a patent attorney.
>
> According to the definition for an 'invention' in Article 2(1) of the Patent Act, the notion of a 'technical idea' and 'creation' presupposes human mental activities. In addition, active participation in the inventive process bestows the status of an inventor under patent law, and a right to a patent is inherently vested in the

> inventor (Article 33(1) of the Patent Act, referred to as "inventorism"). Therefore, the status of an inventor should fundamentally presuppose legal capacity.
>
> While there is no rational basis supporting that designating AI as an inventor would encourage a more proactive AI-driven inventive landscape, there are concerns about potential adverse effects on human-driven innovations, potential erosion of human creativity, potential disruption of research-intensive industries, the prospect of liability ambiguity due to the human developers of AI evading accountability in legal disputes involving AI inventions, and the risk of monopoly of strong AI controlled by a few entities such as large companies, employing patent law as a means for safeguarding their interests. Considering the above, it is difficult to conclude that recognizing AI as an inventor would ultimately advance the technological and industrial development of our society.

An appeal against the above dismissal decision was filed on 28 July 2023 and is currently pending before the Seoul High Court.

EXPLORING A MORE FLEXIBLE INTERPRETATION THAN KIPO AND SEOUL ADMINISTRATIVE COURT'S DECISIONS

Both KIPO and the Seoul Administrative Court relied primarily on article 33(1) (regarding persons entitled to patent) and article 203(1) (regarding information provided in the document of PCT national phase entry) of the Patent Act to determine that the Patent Act limits inventors to natural persons. Nevertheless, article 33(1) of the Patent Act serves as a substantive provision concerning ownership rights, distinct from the formalities surrounding the designation of an inventor in a patent application document. Specifically, this provision does not provide a definition of inventor that applies to the entire Patent Act. Furthermore, the distinction made in article 203(1) between the '(corporation) name' of a corporate applicant and the '(full) name' of an inventor cannot be a sufficient basis to conclude that an inventor under patent law is limited solely to a natural person.

Furthermore, contrary to the US patent law, which explicitly defines the term inventor as the individual who invented or discovered the subject matter of the invention, the Korean Patent Act does not include a provision defining the term inventor. Consequently, it is unclear whether only humans can be inventors, potentially opening the door for a broader interpretation of inventor through flexible legal interpretation. Even in the past, the Korean Patent Act did not explicitly define whether technology publicly disclosed on the internet qualifies as prior art for determining novelty and an inventive step of an invention. Despite this absence, such publicly disclosed technology has been recognised as prior art through flexible legal interpretation that factors in technological advancements.

In addition, in light of the provision outlining the purpose of the Korean Patent Act, which states, '[t]he purpose of this Act is to promote the technological development and to contribute to industrial development by protecting and supporting inventions and promoting the use of inventions' (article 1 of the Patent Act), the necessity to protect AI inventions for the advancement of the AI industry is evident. The KIPO and the Seoul Administrative Court assert that, due to the current state of technology, it is not possible for AI to invent autonomously 'without human intervention', and thus, it is sufficient to designate only humans as inventors. However, instances where AI creates inventions without the participation of a human who meets the traditional criterion set forth by the Supreme Court

(ie, making a substantial contribution to the creation activity of a technical concept) appear to already exist in reality.[6] Furthermore, considering AI's capacity to generate inventions through neural networks in a manner similar to the human brain, it is difficult to distinguish between the creative processes of humans and AI. Consequently, there seems to be no legal basis to differentiate the conferment of inventorship status for these entities.

Although KIPO and the Seoul Administrative Court have determined that an inventor must possess legal capacity, the determination of ownership concerning the right to obtain a patent does not fall within the purview of the formality examination process at KIPO. Instead, such matters are typically addressed and resolved through negotiations among the involved parties. Moreover, well-established legal procedures for resolving disputes involving unentitled rights holders offer a means to effectively settle any conflicts arising over ownership.

Despite these circumstances, both KIPO and the Seoul Administrative Court have adopted a narrow interpretation of legal provisions and applied a passive approach, resulting in the nullification of the filing of the patent application for AI-generated invention. This has fundamentally hindered any further substantive examination.

The rapid pace of technological advancement often outpaces development of corresponding laws and policies, inevitably leading to gaps and challenges. To mitigate these gaps, how legal interpretations are made must be considered comprehensively. Legal interpretations should be geared towards fostering technological progress while minimising legal gaps, ultimately benefiting human progress. In the future, unpredicted technological breakthroughs are bound to arise, each potentially raising similar legal issues. At this time, an appropriate precedent that permits AI to be designated as an inventor will need to be established, to effectively navigate technological progress while upholding legal stability.

FOR PATENT PRACTITIONERS' CONSIDERATIONS UNDER CURRENT KIPO PRACTICE

As mentioned above, KIPO takes a firm stance that designating AI as an inventor is not permissible under the current patent law. Thus, if there is an invention created by AI without involvement of a traditional human inventor (ie, a natural person who has substantially contributed to the creation of the technical ideas), filing a patent application with AI as an inventor may not be the optimal course of action at this time. Instead, a more prudent approach would be to file an application naming the owner or developer of AI as an inventor, even though this may not precisely comply with the patent law, which requires that the true inventor be listed.

Nevertheless, it appears that the ruling of the Seoul Administrative Court in the DABUS case has left room for the potential inclusion of both a human and an AI as joint inventors. The court noted that, 'since only "natural persons" seem to be eligible as inventors under the current Korean patent law, it is reasonable to judge that listing only "AI" as an inventor in the application is not permissible' (emphasis added).[7] On the other hand, as suggested in the decision of the EPO's Legal Board of Appeal,[8] it may be possible to list a human (eg, the owner of AI) as an inventor in the application, while adding a notation in the specification that the invention was created by AI. Most significantly, in the ongoing appeal for the DABUS application, the Seoul High Court may yield a different stance from KIPO and the Seoul Administrative Court, leading to an ultimate shift in KIPO practices and policies.

Endnotes

1 For more details on the Artificial Inventor Project, please refer here. Back to section

2 For more details on DABUS' inventions, please refer here. Back to section

3 Patent Journal, vol 54, No. 07, July 2021, CIPC. Back to section

4 Patent Examination Policy Bureau of KIPO (March 2022) ' White Paper on Artificial Intelligence (AI) and Intellectual Property', pages 17 to 19. Back to section

5 ibid, page 49. Back to section

6 Weibel, Beat 'AI Created Inventions - Digital Inventor computer-Implemented Simulations - Digital Twin' (27 September 2019) WIPO Conversation on Intellectual Property (IP) and Artificial Intelligence (AI). Back to section

7 Seoul Administrative Court Case No. 2022GuHap89524 (30 June 2023), page 7 Back to section

8 EPO Legal Board of Appeal Case No. J 0008/ 20 - 3.1.01 (21 December 2021), page 30 Back to section

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Specialist Chapter: Key Developments on Regulatory Data Protection and Patent Linkage in Mexico

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Summary

IN SUMMARY

This article will analyse two hot topics in the pharmaceutical and biotechnology industries in Mexico: regulatory data protection and the linkage system.

DISCUSSION POINTS

- Regulatory data protection in Mexico
- Mexican linkage system

REFERENCED IN THIS ARTICLE

- North America Free Trade Agreement
- Agreement on Trade-Related Aspects of Intellectual Property Rights
- United States–Mexico–Canada Agreement
- Federal Law for the Protection of Industrial Property
- Industrial Property Law
- Health Supplies Regulations

INTRODUCTION

Mexico is a relevant marketplace for many industries. It is the second-largest pharmaceutical market in Latin America. Thanks to its strategic geographic location, large population and highly qualified human capital at competitive costs, many companies consider it a very appealing investment focus and are nearshoring to Mexico.

Moreover, the Mexican intellectual property (IP) regime has been modernised since the ratification of the North America Free Trade Agreement (NAFTA) and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994, bringing it almost in line with international standards. This benefited the biopharmaceutical industry as innovative activities depend on robust and enforceable IP rights.

More recently, the Mexican legal framework was further strengthened when the United States–Mexico–Canada Agreement (USMCA) substituted NAFTA on 1 July 2020. Consequently, the Federal Law for the Protection of Industrial Property (FLPIP) entered into force that same year to harmonise and re-adapt the Mexican IP system to the obligations now undertaken under this new trade agreement.

Thus, the Mexican IP system can generally secure the interests of pharmaceutical investors and companies. However, the system still faces some implementation hurdles and regulatory gaps since some of USMCA's provisions remain to be fulfilled, and the specific regulations of the FLPIP have not been issued.

This article will analyse two hot topics in the pharmaceutical and biotechnology industries in Mexico: regulatory data protection and the linkage system.

REGULATORY DATA PROTECTION IN MEXICO

Regulatory data protection refers to the exclusive use over a period of clinical or test information submitted to regulatory or health authorities to obtain market approval of a pharmaceutical product by its owner or licensee. Clinical data for evaluating a pharmaceutical product's quality, safety and efficacy is generated by the company requesting marketing authorisation after a great effort in capital and time.

Thus, regulatory data protection for a reasonable period serves as an incentive for investment by pioneering companies in the development and commercialisation of new pharmaceutical products, especially biologics, that are complex molecular medicines derived from living organisms (eg, Humira for treating rheumatoid arthritis or Herceptin for treating cancer).

Biosimilars ('biocomparables' in Mexico) are functional equivalents to a reference innovative biologic product, and are analogous to the relationship between generics (chemically synthesised small molecules) and reference innovative medicines. However, while generics are therapeutically equivalent and molecularly identical to their reference, biosimilars are comparable but not identical to their reference biologics owing to their intrinsic complexity and the great sensitivity of the final product to changes in the manufacturing process (eg, in the case of Heparin).

Hence, regulatory data protection for biologics may also serve as a time to adequately implement pharmacovigilance over the commercialisation of an innovative biologic and correctly assess its effects without interference owing to the concurrent and even crossed administration of biosimilars to patients.

Nevertheless, to date, no specific law in Mexico has regulated protection against unfair commercial use of data submitted before the Federal Commission for Protection against Sanitary Risks (COFEPRIS) for the approval of the sale of drugs.

Before the USMCA, the legal framework for regulatory data protection was provided mainly by articles 82 and 86 bis of the Industrial Property Law (IPL), now abrogated, article 167 of the Health Supplies Regulations (HSR), as well as in paragraphs 5 to 7 of article 1711 of the also abrogated NAFTA and article 39.3 of the TRIPS Agreement. In addition, some 'Guidelines for the protection of confidential information of medicines containing pharmochemicals as a new chemical entity' were published in 2012 by COFEPRIS as an internal document.

According to article 39.3 of the TRIPS Agreement, Mexico as any other WTO member is required to give legal protection to test data directed to the marketing approval of a pharmaceutical product that utilises new chemical entities, provided that the test data is undisclosed and that its origination involved a considerable effort. The test data must be protected against unfair commercial use and disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

Paragraphs 5 to 7 of article 1711 of NAFTA included similar language protection to those in the TRIPS Agreement. Still, NAFTA was more evident when it required the parties to provide a 'reasonable period' of data exclusivity for pharmaceutical products that utilise new chemical entities. NAFTA was considered a more specific standard for protecting clinical data than TRIPS, as it provided a minimum standard of five years of protection from the date market authorisation was granted.

The USMCA is the result of the renegotiations of NAFTA between 2017 and 2018. In the treaty initially approved on 19 June 2019, the strengthening of regulatory data protection was contemplated with:

- at least three years of protection for new clinical information submitted in support of the marketing authorisation of a further indication, new formulation or new method of administration;
- at least five years of protection for new pharmaceutical products that contain a chemical entity that has not been previously authorised; and
- at least 10 years of protection for new pharmaceutical products containing a biological effect.

However, on 10 December 2019, in Mexico City, the Protocol of Amendment to the USMCA was signed, which includes modifications agreed by the three countries, including the issue of regulatory data protection. The Protocol completely removed the text related to the protection of clinical data of biologicals, new indications, new formulations or new administration methods, leaving only one provision (article 20.48) for the protection of at least five years for new pharmaceutical products.

In addition, article 163 of the FLPIP (previously article 82 of the IPL) states that submitting information before COFEPRIS is not considered a disclosure of that information. On the other hand, article 168 of the same law (before article 86 bis of the IPL) establishes that any information required for determining the safety and efficacy of pharmaceutical and agrochemical products using novel chemical compounds will be protected under the terms of the international treaties to which Mexico is party. This article expressly points out the obligation of the Mexican government to adhere to the provisions of international treaties regarding regulatory data protection.

Article 167 of the HSR in turn describes the requirement to submit safety and efficacy data derived from clinical trials for innovative medicines. It states that, in the case of generics, it is only necessary to provide bioequivalence tests without the need for full clinical trials. In this way, it is accepted that the marketing authorisation holder of the reference has already demonstrated the safety and efficacy of the generic.

Therefore, the Mexican government has the obligation to provide regulatory data protection and therefore not to grant marketing authorisations to generics or biosimilars within at least five years of the date of marketing approval of the innovative reference product in Mexico.

Based on the above rationale, even though there is no standard procedure, obtaining at least five years of regulatory data protection through judicial procedures in Mexico has been possible. For some biologics, even more than five years.

Nevertheless, no specific regulation in Mexico provides clinical data protection to balance the market conditions between innovators and generics. There remains an urgent need to create or modify the corresponding legal provisions to clarify and organise the terms, effects and purposes of the protection of clinical data in Mexico, especially for biologics and other types of pharmaceutical products (orphans, new formulations, new indications or use pediatric), promoting fair and loyal competition in the pharmaceutical market. This issue seemed to be going to be corrected with the USMCA, but as previously mentioned, it was left aside at the last moment.

MEXICAN LINKAGE SYSTEM

The linkage system was enacted more than 20 years ago by the Mexican government to improve the communication between COFEPRIS and IMPI to prevent the granting of health registration approvals for generic versions from pharmaceutical drugs covered by granted patents.

Under the linkage system, the IMPI issues the Gazette for Medicines (GM), which contains a list of granted patents organised by international non-proprietary name (INN) of active principle. The GM is published every six months (in February and August), and each gazette substitutes entirely the former. If required, IMPI can issue an extraordinary publication before the indicated period.

Notably, a patent not listed will be equally enforceable through a standard infringement procedure, but it could not be considered when assessing a marketing authorisation.

Patent listings are not related to a particular pharmaceutical product and are not owned by a specific company. Thus, more than one patent could be listed for the same active principle, and a patent could be listed more than once to the extent that it covers more than one active principle.

There are two known ways of listing a patent: a formal petition and a bona fide proceeding, which are not mutually exclusive. The formal petition requires submitting a written request containing some information about the patent before the IMPI, which could be filed at any time after granting a patent. On the other hand, the bona fide proceeding comprises submitting a request for inclusion through the National Chamber of Pharmaceutical Industry (CANIFARMA). The submissions are collected and reconciled by CANIFARMA, who integrates a complete list and submits it to IMPI. Recently, both proceedings can be made using IMPI's digital platform.

If IMPI rejects a patent listing, it is possible to file an appeal before the Federal District Court (FDC). The FDC's decision, in turn, can be appealed in a final stage before a Federal Circuit Court by the affected party. Several patents have been listed following this judicial procedure.

Regarding eligibility, process patents are expressly excluded by statute. Nevertheless, erroneously, IMPI only easily includes active principle and formulation patents. Several appeals have been successful for listing patents referring to products, and numerous second-use patents have been successfully listed by judicial order (around 25 use patents are currently listed). As to biopharmaceutical patents, these patents are eligible for publication in the GM, but it is preferred that the characterisation of the active molecule must be made clear to match the description of the INN. Various biotechnology drug patents have been listed in the GM (more than 100).

Until recently, the system was established by two statutory provisions, one in the Industrial Property Law Regulations (article 47 bis) and the other in the HSR (article 167 bis). The new FLPIP raised the linkage system to law level by including article 162. According to article 162, there could be room in the GM for any pharmaceutical patent, as this article refers to 'a list of patents related to inventions that can be used in allopathic medicines'. It is expected that in the following months, the regulations of the new FLPIP will be issued, and hopefully, they will provide more clarity about the interpretation of article 162. However, the regulations of the former IPL will remain in force until new regulations are in place.

Since the enactment of the system, along with the dossier that is filed before COFEPRIS for obtaining a marketing authorisation, it has been mandatory to file a statement under oath that patents are not infringed by the product, either because the applicant is the assignee of record in Mexico or an authorised licensee of the relevant patents, or because the applicant is not aware of any patents covering the product. Any name change, license, or assignment must be recorded before IMPI to be able to file the statement.

The guidelines issued by the IMPI for the publication of patents in the GM include a process for consultation triggered by COFEPRIS upon the statement of a marketing authorisation applicant. If a relevant patent is detected through IMPI or the GM, COFEPRIS should not grant unauthorised third-party marketing authorisation. However, this burden of work has been an unexpected overload of analysis for examiners at IMPI.

From this regulatory perspective of the system, it is essential to mention that recently, as a follow-up to the implementation of the USMCA in Mexican practice, COFEPRIS attempted to comply with the USMCA notice obligation.

In this regard, article 20.50 of the USMCA establishes that if a party permits, as a condition of approving the marketing of a pharmaceutical product, persons other than the person initially submitting the safety and efficacy information to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the party or in another territory, that party must provide:

1. a system to provide notice to a patent holder (that may include the patent licensee or the authorised holder of marketing approval) or to allow for a patent holder to be notified before the marketing of such a pharmaceutical product that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
2. adequate time and sufficient opportunity for such a patent holder to seek, before the marketing of an allegedly infringing product, available remedies in subparagraph (c); and
3. procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.

Significantly, this provision of the USMCA refers to the 'approved method of use', further supporting the inclusion of second medical uses in the GM. Moreover, it obliges Mexico to establish a notice obligation to the patent holder as part of the linkage system.

Related to the above, COFEPRIS announced directly on its website (which is not the official mean) an opposition form, which must be filled out and submitted before COFEPRIS for any person (patent holder, patent licensee or patent sublicensee) that is affected by the granting of the marketing authorisation of a generic or biocomparable. The opposition form must be submitted directly at COFEPRIS facilities.

COFEPRIS will also publish a weekly updated list of generic and biocomparable marketing authorisation applications and will provide a time frame of only 10 working days from its publication to submit the opposition form against an application. The information provided

in the form will be used for the intragovernmental consultation that COFEPRIS makes to IMPI as part of its process for the authorisation of marketing authorisation.

The opposition form implemented by COFEPRIS does not comply with the USMCA notice obligation at all, as it does not consist of a proper notification to the patent holder of a relevant patent before the marketing of such a pharmaceutical product, and it does not provide adequate time and sufficient opportunity for such a patent holder to seek available remedies. The opposition form puts all the burden on the patent holder, who must monitor the weekly updated lists and then notify COFEPRIS about a possible affectation. Moreover, the update lists do not provide enough information to properly assess if the pharmaceutical product could fall within the scope of a granted patent.

It is well known that policymakers promoting healthcare qualify linkage systems as undesirable and are condemned as contrary to the promotion of public health. However, it is not well understood that the role of linkage systems is not to enforce patents per se or to make the availability of generics harder since the effect of patents will not change if they are listed or not. The true aim of linkage systems is to provide information and certainty.

There is still significant uncertainty surrounding the interactions of pharmaceutical patents with health regulations in Mexico. For example, the linkage system is unavailable for medical devices or veterinary products. Regarding biologics, the role of process patents will increasingly have to be discussed, given the high impact of processes on the quality of the final product.

A well-implemented and fair linkage system will promote fair market competition and make it possible for sanitary and patent authorities to take all measures available to them to maximise the impact of healthcare innovation.

CONCLUSIONS

Strengthening and clarifying the rules regarding regulatory data exclusivity and the linkage system would cause significant gains for Mexico. Both regimes must evolve towards a scheme providing higher legal certainty to all interested parties, promoting fair market competition, and allowing the government to take measures to increase the positive impact of healthcare innovation for the benefit of society at large.

The Mexican legal framework must offer sufficient incentives to achieve the optimal balance between the short- and long-term interests of different sectors of society about health issues – that is, on the one hand, access to future innovations through investment in research and development in a safe way for the patient and, on the other hand, access to existing medicines at lower prices.

Nevertheless, the Mexican IP system provides tools for protecting pharmaceutical and biotechnological innovations and the interests of investors and companies in this industry. Still, careful and detailed assessment on a case-by-case basis must be performed to succeed and maximise the value of these technologies.

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Argentina: A Comprehensive Overview of the Patent Prosecution Landscape

Vanesa Martinez and **Mariano Municoy**
MOELLER IP

Summary

IN SUMMARY

These are the most frequently asked questions regarding patent protection in Argentina but if you have any other do not hesitate to contact the authors from Moeller IP:

DISCUSSION POINTS

- Legal framework and latest developments for patent applications in Argentina
- Forms of protection in Argentina
- Scope of Patentable Inventions
- Patent Enforcement

REFERENCED IN THIS ARTICLE

- International treaties: Paris Convention, TRIPS
- National Constitution of Argentina
- Argentine Patent Law No. 24481, amended by Laws Nos. 24572, 25859, and 27444
- Regulations: Decree No. 260/96, as amended by Decree 403/19.
- Administrative Procedure Law: No. 19549 and Decree 1759/72 (T.O 2017)
- INPI Regulations

WHAT INVENTIONS ARE ELIGIBLE FOR PATENT PROTECTION IN YOUR JURISDICTION AND ARE THERE ANY ELIGIBILITY ISSUES (EG, FOR SOFTWARE OR LIFE SCIENCES INVENTIONS) THAT APPLICANTS MUST NAVIGATE?

In Argentina, inventions can be protected through two main forms of intellectual property: invention patents and utility models. Invention patents grant a term of protection of 20 years from the date of application, requiring novelty, inventive step and industrial application. They cover both products and processes, empowering patent holders to prevent the unauthorized use, sale, manufacture or importation of the patented product or any direct derivative of the patented process.

Utility models, on the other hand, offer a term of protection of 10 years from the date of application and focus on demonstrating a " better use" of the object to be protected, excluding the requirement of inventive step. Utility models protect inventions related only to any new arrangement or form obtained or introduced in tools, work instruments, utensils, devices or known objects that lend themselves to practical work insofar as they involve a better use in the function.

Given that some deadlines and processes vary between the two pathways to protect inventions in Argentina, this article will primarily center on the framework of invention patents in Argentina for simplicity.

In Argentina, the scope of patentable inventions is defined by Article 6 of the Patent Law. It outlines several categories considered as non-inventions, which cannot be patented. These include discoveries, scientific theories, mathematical methods, literary and artistic

works, software programs, methods for intellectual, commercial, and economic activities, and forms for presenting information. Additionally, methods for surgical, therapeutic, or diagnostic treatments for humans and animals, as well as the juxtaposition of known inventions, mixtures of known products, and certain types of living matter and pre-existing natural substances, are also excluded from patent protection.

Furthermore, Article 7 of the Patent Law specifies that inventions contrary to public order, morality, environmental well-being, or the health and life of humans and animals are not patentable. This extends to biological and genetic material existing in nature, as well as biological processes involved in reproduction and genetic processes related to materials capable of self-duplication under normal, natural conditions.

In summary, the Patent Law in Argentina restricts patent protection for specific categories of inventions, ensuring that certain subject matter, like medical procedures, and genetic material, falls outside the scope of patentable innovations. This legal framework aims to strike a balance between encouraging innovation and safeguarding public interests.

Pharmaceutical field: Notably, the pharmaceutical sector faces specific challenges due to Joint Resolution 118/2012, 546/2012, and 107/2012, often referred to as 'the guidelines for the examination of chemical and pharmaceutical patent applications. Among other issues these guidelines states in this field that in the pharmaceutical field, new formulations and compositions, as well as their methods of preparation, are, as a general rule, considered obvious in light of the prior art.

Consequently, obtaining the grant of a patent in any of these technical fields has so far become very difficult, but the chances increase if the application is adapted/restricted to these current regulations.

Software field: Computer programs are excluded from patentability under Art. 6 c) of the Patent Law in Argentina. Although the legislation fails to clarify that computer programs "as such" are excluded, in practice INPI considers methods implemented by computer programs as inventions, provided that they are capable of providing a technical effect that goes beyond the interaction between the computer program (software) and the physical support (hardware) on which it runs.

EXAMINATION TRENDS – WHAT DO POTENTIAL APPLICANTS NEEDS TO KNOW?

Argentina, as well as other countries in the region such as Bolivia, Paraguay, Uruguay and Venezuela, is not a Patent Cooperation Treaty (PCT) member country; therefore, patent applications should be filed within one year starting from the filing date of the priority application, in order to claim priority rights on the basis of Paris Convention.

If the Paris Convention one-year term is lapsed and there has not been public disclosure of the invention, AR patent applications may be filed without claiming priority rights and their novelty and inventive step will be assessed considering only the filing date in Argentina.

If the Paris Convention one-year term is lapsed and the invention has been made public by the inventor at any communication media, Art 5. of Patent Law provides for a one-year grace term for filing the patent application. At the AR filing date, prior disclosures shall be declared, providing evidence. (*)

If the Paris Convention one-year term is lapsed and the PCT application (or any national application of the patent family) has already been published, one-year grace term does not

apply because publications made by any Patent Office are not considered “inventors’ acts” and AR applications are generally rejected at Substantive Examination.

Documentation and key deadlines: To file a patent application in Argentina, there are specific requirements and deadlines to be aware of:

Power of Attorney: The applicant must provide a duly signed Power of Attorney. It should also have Notary or Government Official Attestation of the signing party, along with Consular Legalization or The Hague Apostille. This document must be submitted within 40 working days from the filing date, and it’s a strict deadline with no possibility of an extension.

Documentation: A complete patent application must be submitted together with the filing form, which must include a descriptive memory, an abstract and the claims.

Priority certificates: Only country and priority date are required for filing, there is a 3-month time limit to declare the priority number. Although not required at the filing stage, priority certificates and assignment of priority rights may be requested by the examiner during the examination process. The Assignment of Priority Rights must be signed before or on the filing date in Argentina if the applicant in Argentina is not an applicant of the priority application. The sworn Spanish translation of the priority document shall be submitted within the deadline of 3 months as from AR filing date.

Argentina joined the DAS system in 2019, which allows for the exchange of priority documents. This means that the National Institute of Industrial Property (INPI) can deposit or add the priority document in the DAS system upon request.

Certificate of microorganisms: In cases of biotechnological inventions, a certificate of deposit of microorganisms in a recognized institution according to the patent law of Argentina is required.

Sequence listing: Argentina adopts WIPO Standard ST.26 as of July 1, 2022

Publication: After conducting the preliminary examination, the INPI publishes patent applications within 18 months from the filing date. The applicant may request early publication.

Substantive examination: For patent applications the substantive examination must be paid within 18 months from the filing date of the application.

Annuities: No annuities are due throughout the application process. Accumulated annuities (as from the third one) are due on the first anniversary of the filing date after the grant in Argentina. The remaining annuities must be paid yearly on the anniversary of the filing date.

Submit the application in a foreign language: it’s permitted, but a certified translation and affidavit must be provided within ten (10) working days.”

Key factors to consider in avoiding objections from the patent office - claim set: To minimize potential hurdles with the patent office, it’s essential to take specific factors into account when crafting your patent claims:

Focus on Products or Processes: Ensure that your claims center around products or processes. In Argentina, only claims related to products or processes are accepted. Independent use claims are not allowed, but secondary claims related to use may be accepted in specific technological fields.

Product by process clauses: when a product is difficult to define because of its structure and provided that there is no doubt that the product defined by a process is new and inventive, it may be adequately defined by means of the process by which it is obtained.

Claim categories: Avoid submitting independent claims of different categories, as they will not be accepted.

Claim Preamble and Transition Phrases: Clearly define the field of application in the preamble of your claims and use transition phrases like 'characterized by' where appropriate.

Method of application claims: Note that the criteria for method of application claims may vary depending on the technical field. In certain areas, these claims may meet resistance, as they are often interpreted as use claims.

Taking these factors into account in combination with other relevant elements is vital when drafting patent applications in Argentina to have a greater chance of success.

Amendments to the application/patent: The application as a whole (description + claims) can be amended during the administrative examination process, i.e. until the PTO issues a final decision on whether to grant or deny the application. This means that the application cannot be amended during the appeal or reconsideration action stage (where only the administrative procedures and arguments supporting the patentability of the invention are analyzed). Only obvious mistakes can be amended at this stage.

As a general rule, a granted patent cannot be amended. However, there have been few exceptions to this rule in which it was possible to amend obvious mistakes in the title and the text of the patent.

Divisional applications on the applicant's own initiative: Divisional applications can be filed on applicant's own initiative at any time before a final resolution regarding the parent application has been issued.

If the parent application is rejected (i.e., the PTO issues a denying resolution), the applicant has the right to appeal this final rejection by filing a Request for Reconsideration (a Reconsideration Action). The filing of divisional applications is accepted by the Argentine PTO during the reconsideration action stage. However, this divisional application depends on a positive decision of the appeal: If the rejection of the parent application is confirmed, this divisional application will be rejected too.

The subject matter claimed in the divisional application must be duly supported by the original description and must be clearly distinguishable from the subject matter claimed in the parent application. In other words, the claims of a divisional application cannot overlap with the parent claims. If the claims of a divisional application overlap with the parent claims or with the claims of another divisional application, the patent office will raise a double patenting objection in the first office action issued in connection with the overlapping divisional application. In that case, the applicant will have the opportunity to limit the divisional claims in order to overcome the double patenting rejection.

Applicant can file multiple divisional applications of one parent application, and he can also file a divisional application of a divisional application. In all cases in which a divisional application is filed, the "parent" application on which it depends must be pending at the time of filing the divisional application. Otherwise, the divisional application will be rejected without further processing.

Mechanism for expediting patent application examination: Argentina offers a mechanism for expediting the examination of patent applications under Resolution No. 56/2016. If your application has equivalent patents granted abroad, invoking this resolution can accelerate the priority order for application review. If your application complies with Argentine legislation, it could potentially receive a grant within a few months.

Resolution No. 56/2016 expedites the process for patent applications with equivalent foreign patents. To benefit from this resolution, current claims should align with those of the granted foreign patent, no national antecedents must affect patentability, the substantive examination stage should not have started, Argentine claims should be equal or more limited in scope than the foreign ones, the subject matter should not be excluded from patentability, and the foreign PTO granting the patent should follow criteria similar to those of the Argentine PTO.

This mechanism is applicable for countries with patent examination standards meeting or exceeding those set by Argentine patent law."

HOW CAN APPLICANTS APPEAL OFFICE DECISIONS?

In the INPI AR, the legal means for reviewing an administrative act is through various types of appeals, allowing applicants to challenge these acts.

Reconsideration appeal: This is the administrative means of challenging acts issued by the National Patent Administration (NPA). It is optional. The deadline for filing the appeal is 10 working days from the notification of the act. It is resolved by the NPA and involves an implicit hierarchical appeal in subsidy. It is a fee-based appeal and does not exhaust administrative channels.

Hierarchical appeal: Resolved by the Presidency of the INPI. It is of an autonomous nature. The deadline for filing the appeal is 15 working days from the notification of the act. It is fee-based and exhausts the administrative procedure.

Claim of illegitimity: If an appeal is filed after the expiry of the deadline, it can be dealt with by the Administration for reasons of legality. The consequence is the closure of the administrative and judicial channels.

Appeal before a higher authority: It is filed before the authority which issued the administrative act, namely the NPA, or the presidency of INPI. The issue is then brought to the Ministry of Production for its resolution. The term to file this appeal is of fifteen 15 working days from the notification date of said act.

Reconsideration appeal established by art 72 patent law: Valid only against the Provision that refuses the registration of a patent or utility model. It is resolved directly by the Presidency of the INPI. It is a fee-based procedure. The time limit to file the appeal is 30 working days from the notification of the refusal.

Once all administrative appeals have been exhausted the only available option to seek the overturn of an administrative decision issued by INPI rejecting a patent application is filing a judicial action within 90 days from the date when the challenged decision was issued before the Federal Courts on Civil and Commercial Matters of the City of Buenos Aires against the denial resolution.

In Argentina there are neither special administrative entities nor specialized judicial tribunals in charge of handling the validity and/or enforcement of patent rights

There are two types of judicial proceedings to deal with patent infringement; one based on civil and commercial law (civil proceedings) and the other on criminal law (criminal proceedings).

Different preliminary and final injunctions based on TRIPs and local procedural regulations are available, but while final injunctions may be easily granted together with a final decision, ex partes preliminary measures aimed at stopping infringing activities have become more difficult to obtain after the amendment of the Patent Law in 2003 and the case law that followed.

HOW ARE OPPOSITIONS AND RE-EXAMINATIONS HANDLED IN YOUR JURISDICTION?

In Argentina, there is no formal opposition process for patents. Instead, the procedure involves third-party observations. Third-party observations can be submitted within sixty working days from the publication of the patent application, citing deficiencies in legal requirements for patent approval. These observations, presented in writing with supporting evidence, are limited to questioning the legal prerequisites for patent approval and do not impede the continuation of the process. During substantive examination, the examiner must consider third-party observations related to novelty, inventive merit, industrial applicability, or the legality of the claimed subject matter. Late or unpaid submissions are termed "warning notices." Both warning notices and third-party observations become part of the record, but the examiner does not address warning notices during technical examination. After patent grant, any attempt by a third party to invalidate the patent must occur through judicial means.

INPI cannot declare the nullity of a granted patent so there are no re-examination procedures available but only invalidation/nullity actions as discussed below.

HOW ARE INVALIDATION AND INTER PARTES REVIEWS HANDLED?

Invalidation of granted patents can be filed as either a counter-claim by a defendant in a judicial infringement proceeding or as a direct claim in a judicial invalidation/nullity proceeding. Both types of proceedings are decided by judges on Federal Civil and Commercial Matters.

In order to have standing when filing an invalidation/nullity judicial action the plaintiff must prove having a legitimate interest and in order to achieve the nullity of a patent provide all necessary technical and legal argument to overcome the presumption of validity of the administrative act granting the patent

ARE ANY PATENT-TERM EXTENSIONS AVAILABLE?

No, article 35 of the Argentinian patent law establishes that the exclusive rights of a granted patent last 20 years counted from the filing date, which cannot be extended. Some inventors have argued in courts that this term should be extended in certain circumstances, for instance to compensate for unreasonable delays during the prosecution not attributable to the applicant, but so far judges have rejected such petitions.

WHAT ARE PENDENCY LEVELS FOR THE LAST 12 MONTHS?

Currently, November 2023, the time frame for the examiner at the INPI to initiate the substantive study varies according to the technological field, ranging from 3 to 5 years to receive the first official action. In areas such as pharmaceuticals, biotechnology and chemical compounds, there have been considerable delays for the final resolution of the

patent application up to 10 years in some cases. However, it is relevant to note that INPI is taking significant steps to shorten these delays, including the recent hiring of 7 new examiners. Currently, INPI's two technical departments have a total of 59 examiners.

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Mexico: Bridging National Industrial Design Protection with International Practices

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Summary

IN SUMMARY

In this article, we will explore the primary challenges and opportunities associated with protecting industrial designs in Mexico. We will discuss the current scenery and the emerging trends, emphasising Mexico's decisive actions to harmonise the protection of industrial designs.

DISCUSSION POINTS

- 2018: a turning point for industrial design protection in Mexico
- The 2020 legislative update for industrial designs
- Mexico and the Hague System: an analysis of industrial design protection trends

REFERENCED IN THIS ARTICLE

- Industrial Property Law
- Hague Agreement for the International Registration of Designs

The landscape for protecting industrial designs is constantly evolving owing to the changing demands of national and international regulations. These demands are mainly driven by rapid advancements in technology. As new technologies emerge, they redefine how we conceive, implement and protect designs across different countries. For designers, industries and IP professionals, understanding this landscape is crucial to effectively protect their intellectual property worldwide.

In this article, we will explore the primary challenges and opportunities associated with protecting industrial designs in Mexico. We will discuss the current scenery and the emerging trends, emphasising Mexico's decisive actions to harmonise the protection of industrial designs.

2018: A TURNING POINT FOR INDUSTRIAL DESIGN PROTECTION IN MEXICO

In 2018, Mexico took a significant step to harmonise its legislation on the protection of industrial designs with international standards by introducing a reform to the prevailing Industrial Property Law. This reform brought fundamental changes to align it with international practices.

Evolution Of Protection Terms

A notable example of this effort was the modification of the protection duration for industrial designs. Before 2018, a design was protected for 15 years. With the reform, this duration was shortened to five years, but with the option to renew it every five years, reaching a maximum of 25 years from the filing date in Mexico. This change was implemented to align Mexico's regulations with international standards, mainly those of the European Union Intellectual Property Office (EUIPO).

When this reform was implemented on 27 April 2018, a 30-business-day period was granted for those with pending industrial design applications. They could request the Mexican Patent

Office (IMPI) to apply the new provisions to their applications instead of the rules that were in place at the time of their application.

For applications submitted after the reform's implementation, IMPI automatically applied the new rules. This was irrespective of whether they were divisional applications or whether a request to apply the new provisions had been made. Consequently, this led to design families wherein some designs had a validity of 15 years (those that did not adopt the reform provisions) and others, originated from the same applications, had a validity of five years, renewable up to 25 years.

Clarifying Novelty Requirement

In Mexican legislation, industrial designs that are considered novel and have industrial application are eligible for registration. Regarding novelty, the 2018 reform introduced definitions for the terms 'independent creation' and 'significant degree'. Consequently, a design is recognised as novel when it arises from an independent creation and differs in significant degree from known designs. Although the introduction of these definitions aimed to provide greater clarity to novelty assessment, in practice, it still leads to subjectivity during analysis. These definitions are also similar to those of the EUIPO.

A Step Towards Openness: Publication Of Applications

Another significant change brought by the reform, which offers greater legal certainty to the industrial property system, was the provision that industrial design applications and divisional applications, would be published in the Official Journal of the Federation and subject to public inspection upon the completion of the formal examination. Prior to this reform, these applications were only made public once they had been granted.

THE 2020 LEGISLATIVE UPDATE FOR INDUSTRIAL DESIGNS

Later, on 5 November 2020, Mexico took an additional step forward in its industrial design legislation with the promulgation of a new law. This regulation aligns the country with international standards and brought about other significant advances in the field of industrial designs. These changes, which will be discussed below, were motivated by the entrance into force of the United States–Mexico–Canada Agreement.

Unity Of Design

One of the most notable and innovative elements of this legislation is the introduction of the concept of 'unity of design'. Unlike other jurisdictions, Mexico carries out a substantive examination of industrial design applications. In this process, the novelty of the design in question is evaluated, as well as its unity.

To meet the unity requirement, when an application encompasses several designs, they should have the same name, share novel features and produce the same overall impression. However, the interpretation of the unity criterion can be subjective, leading to complications in the examination process. It is common for design applications to be objected to owing to a lack of unity, requiring the division of the application and submission of divisional applications for the non-elected designs.

It is crucial to bear in mind that if an application receives an objection owing to lack of unity, the corresponding divisional applications must be submitted along with the response to such objection.

Disclaiming Parts Of A Design

Disclaiming parts of a design has become clearer in the new legislation regarding how to distinguish elements that are not part of the claimed design.

In the past, although using broken lines to depict unclaimed portions of a design was common practice, the law did not explicitly support this practice.

With the recent changes, the legislation expressly stipulates that components not claimed should be represented using broken lines. While this method is preferred, the law also allows alternative techniques, such as blurring, shading or outlining contours, provided the distinction between claimed and unclaimed design elements is clear.

However, certain practical challenges remain. For instance, when illustrating a partial design using broken lines, IMPI often requires a name change for the design. Imagine an applicant claiming a bottle design, with parts represented by broken lines to illustrate they are not claimed. In these situations, IMPI generally requires adjusting the design's title to 'portion of a bottle' instead of simply 'bottle'.

The implications of these changes are relevant. For example, within a single application, if one design illustrates an entire bottle with solid lines, and another only the top with broken lines (and the rest in solid lines), labelling the latter as 'portion of a bottle' creates a discrepancy in the unity of design. This is because the designs are not recognised under the same name, leading to potential lack of unity based on differing titles.

These details highlight the importance of accuracy and consistency in naming industrial designs, ensuring clarity and facilitating the IMPI registration process.

Animated Graphic Interfaces

The new regulations also addressed another critical aspect: the protection of animated sequences and graphic interfaces.

A few years ago, when designers sought protection for these sequences or interfaces, they often faced unity objections asking to divide the application, focusing on a single view of the sequence in each submission. This approach posed not only an economic challenge for applicants, as it required multiple registrations for a single interface, but it also misrepresented the dynamic nature of these designs.

It became essential to understand that animated graphical interfaces, especially those within digital applications and platforms, cannot be reduced to individual static views without losing their essence. What makes an animated sequence or interface special is precisely the movement and progression it presents, and it is that dynamic characteristic that requires protection.

Fortunately, current legislation has recognised this need and has evolved to allow the protection of these sequences as industrial designs. This protection is viable as long as the representation provides a clear understanding of the movement or progression. This legislative advance not only benefits creators and developers, but also ensures that design innovations, particularly in the digital environment, get the recognition and protection they sought.

Prior Disclosure

The evolution of industrial designs regulations in Mexico has addressed several key points, one of which is prior disclosure. The earlier Mexican legislation stated that if the inventor or their assignee disclosed an industrial design within the 12 months preceding the application filing or the claimed priority, this disclosure would not compromise the design's novelty.

The new law introduces additional clarification regarding disclosures that are not considered as part of the prior art. Specifically, in addition to disclosures made by the inventor or their assignee within this 12-month time frame, disclosures from third parties who acquired the information directly or indirectly from these primary sources are also considered under this benefit.

However, Mexican legislation specifies publications made in an application, patent or registration by IMPI or any foreign patent office are exempted from this grace period's advantage. This provision reinforces the priority timelines set by the Paris Convention.

MEXICO AND THE HAGUE SYSTEM: AN ANALYSIS OF INDUSTRIAL DESIGN PROTECTION TRENDS

At the international level, Mexico has taken measures to strengthen the protection of industrial designs. Specifically, in 2020, Mexico joined the Hague Agreement for the International Registration of Designs, also known as the Hague System. Since 6 June 2020, applicants have been able to use this system to protect their designs in Mexico and other member countries of the system with a single international application. As of now, there are 79 members.[1]

Despite initial expectations that Mexican designers would frequently use the system, it appears underutilised by national applicants. Of the 3,534 industrial design applications submitted in Mexico in 2022, approximately 28 per cent came from national applicants.-[2] However, the number of international applications originating from Mexican designers remains strikingly low. In contrast, according to the most recent yearly review of the Hague System in 2022, Mexico ranks among the top 20 countries[3] with the most designations.

Therefore, it is crucial for users of this system to understand the particulars when designating Mexico in an international application.

Priority Recognition In Mexico: Challenges And Perspectives

One of the most critical details to note when designating Mexico in an international application is the recognition of priority. According to Mexican law, when a priority is claimed, it is mandatory to submit a certified copy of the priority document, pay the required official fees for its recognition and provide a translation in Spanish within three months of its publication in the International Design Bulletin. If these requirements are not fulfilled, the claimed priority will not be recognised by Mexico.

Although IMPI participates in the Digital Access Service system (DAS), only patent offices have access to this system to obtain the certified copies. However, even when the DAS code is indicated in the international application, it remains pending to make the necessary payment for the official priority fees and to provide the translation of the priority document into Spanish.

Failing to meet these requirements has resulted in the loss of priority rights. Consequently, any document published before the filing date of international application, including the

potential publication of the application that was claimed as priority, is considered part of the prior art. As a result, several designs have been rejected in Mexico for lacking novelty.

On the other hand, even though most applications in Mexico are now submitted online due to the impacts of the covid-19 pandemic, applications originating from an international designation are still processed physically. This means that if the agent in Mexico doesn't already have a power of attorney, both the certified copy of the priority and a physical power of attorney must be submitted within the three-month term following the publication in the International Bulletin. This introduces an additional layer of complexity to the process, emphasising the need for applicants to be fully informed and prepared when seeking priority recognition in Mexico.

Meeting Mexican requirements has become challenging because of the difficulties in sending and receiving hard copy documents in the digital age. However, there is hope on the horizon: IMPI has recently indicated that it is developing a strategy to prosecute such applications online in the near future, which will be a positive step towards simplifying the process.

International Applications Under IMPI Substantive Emination: From Notices To Divisional Filings

Another critical aspect of the international design application process pertains to the notifications of refusal issued by IMPI. First, these notifications are sent by IMPI to the WIPO so the applicant (or appointed representative) of an international application receives this notice through the International Bureau, not from their agent in Mexico. This same procedure applies to notices of allowance and design certificates, even when an agent in Mexico has already attested its personality for that application with IMPI.

Consequently, upon receiving a notification of refusal, the applicant or their representative must coordinate with an agent in Mexico to respond it timely and appropriately. If the Mexican agent has not yet attested its personality before IMPI, they must do so to be able to respond to the refusal.

In contrast to design applications submitted directly to IMPI, where up to two office actions related to the result of the substantive examination can be issued, only one notification of refusal is permitted for international applications. This means that if the grounds for refusal are not overcome in the response, the industrial design application would be denied, forcing applicants to appeal the decision in a separate venue.

The primary objection issued by IMPI for international applications refers to the lack of unity of design. Given what was previously detailed about the requirements that designs must satisfy to be considered under the same design concept, most applications pursuing two or more designs will be rejected owing to lack of unity.

Consequently, when facing this objection, it is necessary to divide the application and submit divisional applications for the non-selected designs. These divisional applications must be filed directly to IMPI, not to WIPO. In this context, unlike the international application, all notifications regarding these divisional applications will be sent to the agent in Mexico rather than the International Bureau, marking a significant shift in the communication and tracking procedure.

Visual Perspectives: The Unwritten Rules Of Industrial Design In Mexico

Another challenge in harmonising criteria for design protection relates to the number of views presented. Although Mexican law does not establish a specific number of views that must be included, some international applications have been rejected because the provided views do not offer a comprehensive understanding of the intended design. This can create confusion and complications for applicants, especially if they are unfamiliar with the unwritten expectations prevailing in Mexico.

For industrial drawings (designs in two dimensions), a single view is often sufficient to provide an adequate understanding of the design. However, for industrial models, which refer to three-dimensional designs, it is more common to present up to seven different views: perspective, front, back, left, right, top and bottom. These views, by offering a representation from various angles, allow for a more complete and detailed understanding of the design in question.

Therefore, when designating Mexico in international applications, applicants should take this into account to avoid unnecessary objections.

Decoding Mexico's Design Protection: The Implication Of Product Identification

Finally, another important consideration when designating Mexico in an international application is that Mexican legislation requires the title of the design to indicate the product to which it is applied. This requirement has led to the rejection of some applications, especially those pursuing two-dimensional designs.

For instance, designs under class 32 of the Locarno classification, which pertain to graphic symbols, logos and surface patterns, have often been rejected because they do not specify the product to which the design is applied.

The challenge posed by the digital sphere is particularly interesting, as a specific design might be applied to a physical product, but the applicant may also wish to protect that design in the digital environment. As in other countries, to protect a digital design, it is necessary to specify a physical product to which it is applied, such as a display screen or another tangible article.

Therefore, although it might seem that one solution could be to specify in the design title that it is applicable to different products, IMPI's position is that the design can only specify its application to a single product.

A consequent question is: what about designs intended for products not explicitly mentioned in the title? Would they receive implicit protection when registered for other products?

According to Mexican law, infringement arises when an industrial design is used that either does not differ to a significant degree from a protected design or utilises combinations of characteristics from such a protected design.

Therefore, we believe that as this provision is not narrowed down to the Locarno classification or any other statement made in the application papers, the specification in the title of the product to which the design will be applied should not be viewed as the boundary of industrial design registrations.

In spite of these challenges, the Mexican industrial design system remains resilient. We are confident that, with the evolution of new technologies, Mexican legislation will continue to define new regulations and criteria to adapt to them, offering the best protection for industrial designs.

Mexico's commitment to industrial design protection is evident through its alignment with key international systems, including the Hague System. While there is always room for improvement in the field of industrial property, especially given the constant evolution of new technologies and products, the current framework effectively safeguards intellectual assets. For those looking to protect their designs, Mexico stands as a strategic option, offering both efficiency and robustness in design protection.

Endnotes

1 https://www.wipo.int/wipolex/en/treaties/ShowResults?search_what=C&;treaty_id=9. Back to section

2 https://www.gob.mx/impi/documentos/instituto-mexicano-de-la-propiedad-industrial-en-cifras-impi-en-cifras. Back to section

3 Hague Yearly Review 2023 – published by the World Intellectual Property Organization: https://www.wipo.int/edocs/pubdocs/en/wipo-pub-930-2023-en-hague-yearly-review-2023.pdf. Back to section

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Specialist Chapter: Procuring Patent Protection for AI Inventions

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Summary

IN SUMMARY

This article discusses patenting strategies for artificial intelligence (AI) inventions in today's AI landscape. It also reviews the current legal framework for patenting AI technology in the United States and examines two case studies of AI inventions.

DISCUSSION POINTS

- How to identify AI inventions in today's AI framework
- How best to protect different types of AI inventions with patents
- What are the obstacles in patenting AI?

REFERENCED IN THIS ARTICLE

- *Trinity Info Media, LLC v Covalent, Inc*
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- *In re Bd of Trustees of Leland Stanford Junior Univ*
- *SAP Am, Inc v InvestPic, LLC*
- *CardioNet, LLC v InfoBionic*
- *McRO v Bandai*
- United States Patent and Trademark Office, 2019 Revised Patent Subject Matter Eligibility Guidance
- Open AI

Today, generative AI is a groundbreaking field. Generative AI uses large language model (LLM) technology that helps with natural language processing and understanding. ChatGPT by OpenAI is a well-known chatbot that implements LLMs. Since its release in November 2022, ChatGPT became a pioneering generative AI model owing to its accessibility and ability to generate coherent and contextually relevant text in a conversational manner. OpenAI is also rolling out its commercialised platform known as GPT Store.[1] The GPT Store allows various generative pre-trained transformer (GPTs) in different categories to become searchable and customisable for a user to build their own generative AI applications. This marketplace to monetise customised GPTs is similar to the App Store framework, where customised GPTs are hosted, developed, promoted and evaluated on OpenAI platforms, providing a marketplace for tailored AI models and services for specific tasks.

Owing to advancements in AI, companies are pursuing their intellectual property rights to keep and obtain a competitive edge in the AI landscape. Since January 2020, over 20,000 US patent publications relating to a 'neural network' or 'machine learning' have been filed. In this article, we will discuss strategies to procure patent rights over AI technology: what are AI inventions? How best to protect them with patents? What are the obstacles?

IDENTIFYING AI INVENTIONS

Today, the AI framework has multiple actors. Identifying AI inventions in the AI framework, the associated actors and the owners are a crucial step in any intellectual property strategy.

Patenting AI Frameworks

AI In A Product

AI inventions can be integrated in different products, including robotic surgery tools, autonomous driving vehicles, and virtual and augmented reality. To obtain patent protection, an applicant should identify an innovative AI component within the AI product and assess whether the innovation lies within the AI component or within a particular application of the AI component within the product. Consider a vision neural network model that is engaged in autonomous driving to detect road conditions by capturing images of a surrounding environment. An applicant should assess whether the novelty lies in training and inference of the vision neural network model, or in how a control mechanism uses the output of the vision neural network model. A detailed case study of a robot surgical product involving AI is also discussed below.

AI As A Module

AI inventions can be contained in a 'module'. AI companies develop neural network modules that are then deployed on their servers. In this scenario, the AI architecture (design of an AI structure, including types and layers of a neural network), training and finetuning of AI (using data to teach and fine-tune the neural network to achieve certain functions), AI testing (using the trained neural network to perform certain functions) and AI deployment (releasing the neural network into the real world to perform tasks) are all conducted by the same company. Therefore, a patentee may pursue a patent strategy directed to building a new AI model architecture, training the AI model with a training objective that achieves a certain function and using the AI model to perform a new task at inference in the real world.

AI As A Service

To streamline AI resource utilisation, downstream AI companies may use AI as a service (AIaaS). In a nutshell, AI companies may access and utilise AI tools, algorithms and models (eg, a commercialised GPT model subscription) provided by a third-party provider, without considerable investment in hardware, software and expertise. In this scenario, a patentee should identify components and functions within an AI product that are built on top of AIaaS and are owned or conducted by the patentee. For example, the patentee may pursue a patent strategy directed at how systems communicated with external AI models to perform certain tasks via application programming interfaces (APIs).

AI As A Marketplace

In a foreseeable future of AI marketplaces, an AI ecosystem may be created that builds, trains, publishes, trades and uses customised AI models by multiple parties. For example, the GPT Store allows creators to build and sell their own GPTs. In this ecosystem, AI inventions may occur at different levels: building and pretraining of the original GPT (eg, performed by the original GPT provider), hosting and providing APIs that customise the GPT (eg, performed by the marketplace platform), facilitating the publication and transactions of customised GPTs at the AI marketplace (eg, performed by the marketplace platform) and building any customised AI infrastructure by purchasing or subscribing to customised GPTs from the marketplace (eg, performed by a downstream AI company). Therefore, a patentee may need

to identify the appropriate actor within the AI ecosystem to obtain patent coverage and minimise divided infringement.

Patenting AI Data

It is not a secret that AI models use and produce data. This data can be protected using patents.

Training Data

Training data is a secret sauce that sets an AI model apart from its competitors. AI models can be trained on public datasets that are in a public domain, on a combination of public and private datasets, or only private datasets that are often kept as trade secrets. However, with the onset of regulation at state and federal levels directed at keeping AI models fair, unbiased, and responsible, keeping the training data a trade secret may no longer be a viable option. There are options, however, for companies seeking to obtain patent protection for their training data:

- Unique data characteristics, including data structures and constituents may be claimed together with the AI model.
- When an AI model combines different training datasets (eg, public and private or private and private), the claims may be directed at the combination or at specific steps for achieving the combinations.
- AI models can process different datasets differently. Often, AI models are pre-trained by one company on one dataset and are fine-tuned on a specialised dataset for a particular purpose by a different company. This may result in different training data passing through different layers of the AI model, and claims may be directed to the type of training data that trains different layers and how the data is split during AI model pre-training and finetuning.
- Sometimes synthetic data is created because training data is unavailable or is difficult to obtain. Synthetic data emulates scenarios in a real-world environment that are not covered by the original training dataset. Steps directed to identifying scenarios that are not covered by the original training dataset and creating synthetic data are all eligible for patent protection.
- When an AI model is trained with training data, different training samples can be given different weights. In other words, not all samples are treated equally. Identifying which samples in the training dataset should be given more or less weight during training and which samples may be suppressed and ignored may also be covered by a patent.

AI Inputs

A trained AI model receives data as input and generates an output as a result. The input to the AI model can largely be protected in ways similarly to the training data. In some instances, an input to an AI model can be a combined input from multiple sources, including an input from multiple AI models and an input augmented with retrieval augmented generation techniques. Patent protection may be directed to novel techniques for combining different data that serves as input to an AI model.

AI Outputs

Today, AI outputs created by an AI model that is an inventor are not eligible for patent protection in United States.[2] On the other hand, AI outputs created by an AI model that serves as a tool in the inventive process are protectable. Protecting AI outputs as a product-by-process (eg, claiming a genome sequence generated by a particular AI model using particular input data) is also an option. Whether AI can or cannot be an inventor is a question that is being considered by the US Patent Office and Congress in the United States, and other bodies worldwide. Thus, one should be mindful to changes, if any, to AI inventorship. Further, there is ongoing research into LLM models that create three-dimensional outputs, impacting the medical devices, 3D printing, life sciences and material science industries. In addition to utility patents, the non-functional appearance of the three-dimensional outputs can be also be protected by design patents.

OVERCOME OBSTACLES TOWARDS PATENTING AI

Obtaining patents for AI technologies present unique challenges under the current legal framework, particularly in meeting the eligibility requirements under section 101 of the Patent Act, because AI technologies often involve software and mathematical algorithms. The uncertainty in the current state of section 101 law is largely attributed to the two-step Alice framework for eligibility, established by the Supreme Court's 2014 decision inAlice Corp Pty v CLS Bank Int'l, 573 US 208 (2014). Despite these challenges and uncertainty in section 101 law, we will delve into recent case law for guidance relevant to AI technologies and then explore practical considerations for successfully obtaining strong AI patents.

District Courts: Rule 12(b)(6) Motion To Dismiss AI Patent Claims On Section 101 Grounds

In U.S. patent cases, Rule 12(b)(6) allows defendants to seek early dismissal under section 101. If granted, the case is dismissed without the plaintiff having the opportunity to engage in extensive discovery, which is crucial for gathering evidence and building a stronger case.

Recent cases (eg,Power Analytics, Health Discovery and Recentive), witnessed successful 12(b)(6) motions dismissing AI patent claims.[3] The courts rejected arguments based on differences from the human brain: for example, 'machine learning algorithms are unique since they process information differently from how the human brain could or would' or 'humans could not perform the patented processes, because the data and algorithms are too complex' (see, eg, Recentive at 17-20). These decisions underscore the importance of carefully crafting strong AI patent claims resistant to 101 challenges.

Federal Circuit

It is difficult to apply Alice with consistency as illustrated in Federal Circuit section 101 cases, hindering a unified interpretation. Despite this complexity, we distil guidance on effective claim drafting for AI technologies, addressing section 101 challenges: Trinity, Stanford and SAP found claims ineligible, emphasising abstract nature, while CardioNet, Thales and McRO found claims eligible because of tangible technological improvements.

Federal Circuit: Claims Not Eligible

Trinity Info Media, LLC V Covalent, Inc, 72 F.4th 1355 (Fed. Cir. 2023) (Trinity)

The court held that a human being incapable of matching processing speed does not make an abstract process patent eligible. The Court explained that 'Trinity's asserted claims can be directed to an abstract idea even if the claims require generic computer components or require operations that a human could not perform as quickly as a computer.'[4]

In Re Bd Of Trustees Of Leland Stanford Junior Univ, 991 F.3d 1245 (Fed. Cir. 2021) (Stanford)

The patent describes a method for more accurate prediction than prior art in genetic sequencing. The Court determined this is an improvement to an abstract idea, not a technological improvement. The Court concluded that the claims were directed to abstract ideas: 'the use of mathematical calculations and statistical modelling,' and this was 'merely an enhancement to the abstract mathematical calculation of haplotype phase itself.'[5] The Court distinguished McRO and CardioNet, holding that they 'involve practical, technological improvements extending beyond improving the accuracy of a mathematically calculated statistical prediction'.[6]

SAP Am, Inc V InvestPic, LLC, 898 F.3d 1161 (Fed. Cir. 2018) (SAP)

The Court found claims directed to statistically analysing investment information and reporting the results to be abstract.[7] Specifically, the Court distinguished McRO on the grounds that McRO was directed 'to the creation of something physical', unlike the quantitative predictions in SAP.

Federal Circuit: Claims Eligible

CardioNet, LLC V InfoBionic, 955 F.3d 1358, 1368 (Fed. Cir. 2020) (CardioNet)

The District Court determined on a Rule 12(b)(6) motion that a medical device patent was ineligible as it was directed at an abstract idea. The Court reversed, finding that the claims are instead directed to 'an improved cardiac monitoring device', confirmed by various specific technological improvements detailed in the written description. While the claims provide a statistical prediction, the Court found that they provide an improvement to cardiac monitoring technology as opposed to an abstract idea by providing an improved prediction of heart arrhythmia based on heart monitoring data.

Thales Visionix V United States, 850 F.3d 1343, 1348 (Fed. Cir. 2017) (Thales)

The claims are related to an inertial tracking system. The Court found that the claims, which admittedly included mathematics, were patent eligible, where 'the application of physics create an improved technique for measuring movement of an object on a moving platform'.[8] The Court found that the claims here resulted in a system that reduces errors in an inertial system that tracks an object on a moving platform.

McRO V Bandai, 837 F. 3D 1299, 1311 (Fed. Cir. 2016) (McRO)

Often referred to as the 'animation invention' case, the claims related to automated lip synchronisation for animated characters. The Court found the claims patent-eligible, emphasising the specific improvement in computer animation and the use of rules to automate a previously manual process.

USPTO Guidance

The USPTO has provided examples for guidance on patenting AI inventions, including its 2019 Revised Patent Subject Matter Eligibility Guidance and ex parte Hannun, 2018-003323 (1 April 2019) (designated as 'informative') (Hannun). These examples were provided in 2019 and incorporated into the Manual of Patent Examining Procedure in 2020, but do not reflect the latest developments from the Federal Circuit. We expect that the USPTO will provide new guidance in 2024, following President Biden's executive order (EO) on AI issued on 30 October 2023.

Practical Considerations For Patent Application Drafting

Use of machine learning alone doesn't make claims eligible (see Power Analytics, Health Discovery and Recentive). Examiners, aligning with court decisions, will increasingly treat generic machine learning models and iterative training methods akin to generic computer components for section 101. Mere distinctions from a human brain may not suffice for AI claims' eligibility.

Provide details. Courts seek specifics about the model and functions, for example: how the machine learning engine is configured and any particular structure and processes for performing the functions (eg, how to compare the real-time and predicted values, how to pick the threshold values and how to update the model).

Avoid description only in broad functional terms with little guidance on model parameters or training technique. Be careful with the description of using 'any suitable' machine learning or iterative training techniques. Instead, describe specific functions, parameters and training techniques, and emphasise the inventiveness of these specific features.

Emphasise the AI invention's link with 'something physical'. Courts underscore the importance of physical improvements, including the use of mathematics to achieve improvements in physical things (see CardioNet, McRO and Thales). For instance, frame outputs as 'generated' (eg, audio, images, videos, text converted from speech and code) rather than 'predictions' where applicable (see Stanford and SAP). For example, in AI for material discovery, outputs can be framed as alloy compositions and treatment parameters.

Articulate additional advantages beyond improved prediction accuracy. Merely stating prediction or enhanced prediction without tying it to physical improvements may not suffice for eligibility, as seen in Stanford and SAP.

Stay adaptable to ongoing developments. Notably, President Biden's EO on AI, issued on 30 October 2023, requires the USPTO director to – in an effort to address innovation in AI and critical and emerging technologies – publish guidance addressing inventorship and the use of AI and other considerations at the intersection of AI and IP on patent eligibility. Keep abreast of legislative changes and court decisions to enhance AI patenting strategies. Align drafting with recent legal developments for robust AI patent portfolios.

AI CASE STUDIES

Below are case studies that showcase patent strategies for AI inventions.

Case Study 1: AI Assisted Surgical System

Consider an AI company training an AI model to assist in a well-known type of laparoscopic surgery. The trained model reviews a video of a surgery in real time and makes surgical recommendations. The recommendations are displayed via icons on a graphical user interface that is viewable by the medical team. Eventually, portions of the surgery may be controlled by the surgical system in response to the trained model's recommendations and predictions.

To shape a patent strategy for this AI surgical system, the first question is whether the company wishes to disclose sufficient detail of the AI architecture and training to enable others to develop a similar model without undue experimentation. If the company is unable to disclose sufficient detail, a utility application may eventually be rejected by the USPTO for lack

of enablement or as an abstract idea under section 101. One option is to focus on protecting aspects other than the model itself. For example, the icon displayed on the graphical user interface may be eligible for a design patent. Design patents protect the design of the icon and do not require details of the AI model to be disclosed. Alternatively, if the company is able to disclose sufficient detail but does not want to publish these details prior to obtaining patent protection, the company can file a utility patent application with a non-publication request. While the non-publication must be withdrawn if and when the company decides to file internationally, filing a non-publication request is a way of keeping the technology a secret until a patent issues.

Assuming the company is able to disclose sufficient details regarding the model, the next key question relates to patent eligibility and is, what makes this invention special? Is there something unique about the training data or the model itself? Does this invention improve the functioning of a computer or improve a technical field? What is the system doing that could not be done by a human? The improvements should be detailed in the specification of a utility patent application. If the model is trained in a conventional manner using publicly available datasets to generate a recommendation that could be generated by a human, then it would likely be beneficial to include utility claims describing the icon output or describing the iteration of the surgical system that controls portions of the procedure in response to the model's recommendation and predictions. If the model itself or the training of the model is unique, then patent claims can be drafted focusing on the use of the model as well as the training of the model.

Case Study 2: AI Outputs

Assume the company uses AI to improve a previously known 3D product by inputting requests and refining the AI model's output. Unlike case study 1, meeting the enablement requirement will likely not be difficult if known manufacturing techniques can be used to make the improved product. Moreover, patent eligibility is less of a concern when the claimed invention is an improved 3D product. But the claim strategy may need to be carefully assessed in view of inventorship. For example, as the AI model itself cannot be an inventor, patent claims shall not be directed to AI output data alone. If patent claims are directed to the final product, however, the AI model merely served as a tool for the personnel who provided inputs and refined the AI model's output, and it is the personnel who discovered the improved product using the AI model. As such, the personnel who utilise the AI model to arrive at the final product are identified as inventors when claims are pursued for this improved product. Moreover, the company could pursue design patent protection for the improved product if the improved product involved a new design.

Endnotes

1 GPT store, 'Discover the GPTs and plugins of ChatGPT' (https://gptstore.ai/). ^ Back to section

2 Thaler v Vidal, 43 F.4th 1207 (Fed. Cir. 2022) ^ Back to section

3 Power Analytics Corporation v Operation Technology, Inc, C.A. No. 16-1955 (C.D. Cal. July 13, 2017) (finding claims using a 'machine learning engine' to be ineligible since the patent 'does not specify how the engine is configured'); Health Discovery Corp v Intel Corp, 577 F. Supp. 3d 570 (W.D. Tex. 2021) (holding ineligible claims on a machine learning algorithm as directed solely to unpatentable mathematical ideas);Recentive v Fox, DDE-1-22-cv-01545 (D. Del. Sep. 2023)(finding claims using machine learning algorithms ineligible). Back to section

4 Trinity at 1364. Back to section

5 Stanford at 1250-1251. Back to section

6 id. at 1251 Back to section

7 SAP at 1161. Back to section

8 Thales at 1349. Back to section

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Germany: UPC Impact and Legislative Shifts Make Germany a Venue of Choice

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Summary

IN SUMMARY

This article discusses the recent implementation of legislative reform in the country's national patent law and the launch of the new European Unified Patent Court (UPC). We highlight the importance of Germany as a litigation venue for protecting innovation. On the European level, there have been interesting new EU legislative reform proposals, not only in the areas of patent law but also regarding supplementary protection certificates and FRAND licensing, as well as two important decisions of the EPO Enlarged Board of Appeal on plausibility (G 2/21) and priority (G 1/22 and G 2/22).

DISCUSSION POINTS

1. Launch of the UPC
2. New criterion for injunctive relief claims against infringers
3. Supplementary protection certificates
4. Compulsory licensing
5. Entitlement to priority (G 1/22 and G 2/22)

REFERENCED IN THIS ARTICLE

1. German Patent Act
2. *10x Genomics v NanoString*
3. European Court of Justice decision C-44/21
4. Wärmetauscher
5. Truvada
6. *Huawei v ZTE*

LAUNCH OF THE UPC

In February 2023, Germany deposited its instrument of ratification with the Secretariat of the Council of the European Union, launching the countdown for the UPC to open its doors in June 2023. The Unitary Patent and UPC system was designed to offer a simplified, efficient and cost-effective route to patent protection and litigation, obviating the need for multinational validation, invalidity or infringement proceedings. The UPC's first patent infringement hearing took place in Germany before the Munich Local Division and resulted in the first preliminary injunction being issued in September 2023 (10x Genomics v NanoString-).

Under the UPC system, Germany hosts four local divisions (Düsseldorf, Munich, Mannheim and Hamburg) and one branch of the central division (Munich). This is the highest number of UPC courts in any of the member states. Given the high importance of German courts for international patent litigation, it is expected that the four German local divisions will play a

major role in the jurisdiction of the UPC. A look at the present case statistics confirms that this is already the case.

Klaus Grabinski, former judge at the Federal Court of Justice in Germany, has been appointed the president of the Court of Appeal. In all, 105 judges have been appointed: 37 legally qualified judges and 68 technically qualified judges. The technically qualified judges are experienced national patent practitioners or judges ensuring the delivery of high-quality decisions. By far the largest number of legally and technically qualified judges (over one third) comes from Germany.

In a first decision on a validity challenge, the central division in Munich assessed the admissibility of a revocation action filed by Sanofi on the same day as an infringement action was filed by Amgen at the local division in Munich in the case No. UPC_CFI_1/2023. As a general rule, a revocation action should be brought before the central division unless an infringement action between the same parties concerning the same patent has been filed before a local or regional division. In the latter case, the revocation action can only be brought before the same local or regional division. Amgen filed a preliminary objection to the inadmissibility of Sanofi's revocation action, arguing that the infringement action was filed first, as evidenced by the information available on the CMS. The UPC judge rejected the preliminary objection, noting that Sanofi's revocation action was filed on 1 June 2023 at 11.26 a.m., while Amgen's infringement action was filed at the sub-registry of the Munich local division on 1 June 2023 at 11.45 a.m.; that is, less than half an hour later. This decision underscores the importance of promptly filing actions, as even small delays can have a significant impact on the potential bifurcation of infringement and revocation actions, and ultimately influence the litigation strategy.

PRELIMINARY INJUNCTIONS WITHOUT PRECEDENT FIRST-INSTANCE OPPOSITION OR NULLITY PROCEEDINGS

Preliminary injunctions have always already been a powerful weapon in German patent litigation as they allow the patentee to obtain an injunction against a patent infringer within weeks by way of a 'mini trial'. In addition to proving the patent infringement and the urgency of the case, the issuance of a preliminary injunction in a patent infringement case in Germany (regardless of whether before a national court or German UPC division) generally requires the substantiation of the patent's validity. For this criterion, at least before the most important patent appeals courts in Düsseldorf, Munich and Karlsruhe, it is not enough that the patent has been examined and granted by a Patent Office. Instead, it is usually required that the patent has previously been upheld in first-instance opposition or nullity proceedings.

After a referral of the regional court of Munich I, the European Court of Justice ruled in its decision C-44/21 in April 2022 that national case-law, "under which applications for interim relief for patent infringement must, in principle, be dismissed where the validity of the patent in question has not been confirmed, at the very least, by a decision given at first instance in opposition or invalidity proceedings", is precluded by the Enforcement Directive. Following this decision, some German practitioners expect more preliminary injunctions to be issued from patents without precedent first-instance opposition or nullity proceedings in the future. However, most practitioners expect no substantial change in the future decisions of the German courts, as preliminary injunctions from patents without preceding validity proceedings could already be granted before in exceptional cases. Needless to say, it will be interesting to see which criteria the UPC will apply.

Following decision C-44/21, some German courts have taken a more applicant-friendly approach, while others do not appear keen to alter their previous approach to the general requirement of confirmed validity for a preliminary injunction. In view of the C-44/21 decision, actors on both sides need be prepared to present their substantive arguments on the patent's validity in a timely fashion.

REVISIONS TO THE GERMAN PATENT ACT

In an effort to simplify and modernise the law and to expedite patent proceedings, the German parliament ratified a bill to revise the Patent Act, the first substantive change since 2009. The new version of the law entered into force on 18 August 2021.

QUALIFIED OPINION

One of the major changes to come with the revision is the introduction of a six-month period for the Federal Patent Court to provide a qualified (preliminary) opinion on the merits of a case in invalidity proceedings. Germany has a bifurcated system for national patent litigation, whereby infringement and invalidity cases arising from the same patent are handled by different courts – infringement by the civil courts and invalidity by the Federal Patent Court. Infringement proceedings can be stayed in cases of serious patent validity doubts. This occurs in about 20 per cent of cases. But under the bifurcated system, a (generally faster) civil court judgment on infringement may only be vacated much later by the (generally slower) Federal Patent Court ruling on invalidity. This scenario, which is sometimes referred to as an 'injunction gap', is specifically tackled by the changes to the Patent Act. These aim to better align patent infringement and nullity proceedings by offering the infringement courts a qualified view on patent validity within a more reasonable time frame, in order to stay proceedings if necessary. Currently, the Federal Patent Court seems to be meeting the challenging six-month schedules that have been set, although this may change as the Court has experienced a drain of technical judges to the UPC and is currently understaffed in many senates.

Only time will tell whether the changes will really enhance the synchronicity of the bifurcated system or whether they will simply entail more work at the Federal Patent Court. It is undeniable that the six-month time limit places a much higher burden on the Federal Patent Court. For the parties, this also means a significantly tighter schedule to file their full arguments and evidence. Under the new law, there is a statutory two-month deadline for the patentee to present its detailed defence from receipt of the nullity complaint. Only in exceptional circumstances can this be extended by one further month. Under the new provisions, patentees are therefore advised to carefully review and prepare validity defences well in advance of starting an infringement action. Also, since it is essential for the patentee to receive a favourable preliminary opinion in invalidity proceedings in order to avoid a stay of the parallel infringement proceedings, patentees are well advised to present their complete defence against the invalidity action as early as possible in the proceedings so that the Federal Patent Court can properly consider it in its preliminary opinion. While the preliminary opinion on invalidity cases is now usually issued within the six-month time frame, the total duration of first instance proceedings at the Federal Patent Court (on average about 1.5 to 2.5 years) is still much longer than for infringement proceedings (on average about 10–14 months).

NEW CRITERION FOR INJUNCTIVE RELIEF CLAIMS AGAINST INFRINGERS

Another change to the German Patent Act concerned one of the most prevalent tools of patent enforcement against infringers in Germany: injunctive relief (ie, a cease-and-desist order). The Patent Act states that patentees can order infringers to cease and desist from using, selling and importing, among other things, a patented technology. In its 2016 Wärmetauscher ruling, the Federal Supreme Court added an extra unwritten exclusion criterion whereby injunctive relief can be denied in exceptional cases if the court finds that it would pose a disproportionate burden or hardship on the infringer and therefore breach the fundamental principle of good faith. This principle of proportionality brought the German injunction statute in line with EU standards, and specifically the Enforcement Directive.

The proportionality test has now been codified in the new law, making the examination of injunctions more transparent. But experience has shown that there has been little change to the practical implementation of the statute. Indeed, patent practitioners do not expect the revision to change Germany's position as one of the most patentee-friendly litigation venues in Europe.

In addition, the legal consequences in cases of disproportionate burden remain at the courts' discretion. This means that, instead of excluding the injunctive relief, courts can decide to what extent the exclusion should apply. For example, the court may set a grace period for the infringer to implement design-arounds or to sell its remaining stores of the infringing technology – at a price, of course.

To support a fair and flexible approach while still protecting patentees' rights, the new revision explicitly introduces a reparations clause by which the court can – in the same decision – order the infringer to pay a fair and commensurate reparation to the patent owner if a grace period is set. Importantly, this temporary exclusion of injunctive relief does not legalise the infringement for the grace period and will therefore not affect the patent owner's claim to damages. After more than two years of experience under the new law, it seems fair to say that patent owners can be confident that the German courts continue to be a particularly patent-friendly venue for infringement proceedings, and that injunctive relief will remain a powerful weapon in the IP arsenal of patentees litigating their patents in Germany.

SUPPLEMENTARY PROTECTION CERTIFICATES

Supplementary protection certificates (SPCs) for medicinal products are a form of patent extension that can be granted to compensate patent owners for the shortened effective patent life on account of the extended period that it takes for regulatory certification of such products. One of the requirements for granting an SPC is that the product must be 'protected by a basic patent in force'. It was initially unclear, however, to what extent this applies to a product composed of several active ingredients having a combined effect, particularly when that combination is not expressly mentioned in the claims of the patent.

The German Federal Supreme Court applied the principles set out by the European Court of Justice (ECJ) in its decision C-121/17 in the German Truvada case (X ZR 172/18). In this decision, the court found that:

- the combination of two active ingredients is generally not protected by a patent where the claims consider one of those active ingredients to be optional; and
- in order to fulfil the 'specifically identifiable' requirement based on the prior art at the priority date, it is not enough if one of the active ingredients is neither functionally nor structurally defined.

As a take-home message for patent applicants in cases that could serve as a template for an SPC application, it is important to define any envisaged combination treatments at least non-optionally in the claims, and to make sure to either functionally or, if possible, structurally define all the active ingredients in the description.

Currently there is no centralised process for SPC applications in the EU. Instead, SPCs must be applied for through national patent offices. On 27 April 2023, the European Commission presented its proposals for the development of a more unified SPC system. The first set of proposals aims to introduce a centralised procedure for the grant of national SPCs and a single SPC database. The second set of proposals seeks to implement a unitary SPC protection for the member states participating in the unitary European patent system and a unitary examination procedure for national SPCs and SPCs in the field of pharmaceuticals and plant protection products. A uniform European SPC system would be capable of further strengthening Europe as a research location in the long term due to less bureaucracy, lower costs and less use of resources for companies when they apply for supplementary protection certificates. Furthermore, the availability of a unitary SPC could be an additional advantage of using the UP system. However, whether the European Union Intellectual Property Office (EUIPO) in Alicante, Spain, is the right competent body for unitary SPC applications, examination and grant – and for the centralised SPC application and examination process (as initially proposed) – seems questionable given its lack of experience in patent matters.

COMPULSORY LICENSING

Patent owners seeking injunctive relief against alleged infringers based on an SEP and holding a dominant market position must adhere to the framework laid out by the ECJ in its 2015 Huawei v ZTE decision (C-170/13). This includes, among other requirements, informing the alleged infringer of the patent and making a FRAND licensing offer if the alleged infringer shows willingness to negotiate. All this must occur prior to initiating infringement proceedings.

Currently, EU member states each have their own compulsory licensing regimes. On 27 April 2023, the European Commission presented its proposals for changes in relation to compulsory licensing of patents in crisis situations and reforms to the Standard Essential Patents (SEPs) system. The proposal is for non-exclusive, non-assignable compulsory licences that would have a scope and duration limited to the purpose for which they were granted (and that of the relevant crisis). These would be strictly limited to 'crisis-relevant products' and to the territory of the Union. The proposals would further introduce an SEP register, database and essentiality checks; expert opinions on SEP aggregate royalty; FRAND determination by means of conciliation in lieu of litigation; SME support measures; and the establishment of a 'Competence centre' at the European Union Intellectual Property Office (EUIPO), enabling the EUIPO to set SEPs licence fees worldwide.

PLAUSIBILITY AFTER G 2/21

The role of plausibility in admitting post-published data for inventive step and sufficiency was referred to and has now been decided in G 2/21 by the Enlarged Board of Appeal (EBA), the highest judicial authority at the European Patent Office (EPO).

In its decision, the EBA held that post-published data evidencing a technical effect cannot be disregarded solely because the data was not public at the filing date. The guiding principle on whether a technical effect shown by post-published data can be relied upon is now whether:

> the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention.

The abstract formulation of this principle was presumably deliberate, to allow for sufficient flexibility and discretion in future decisions of the Technical Boards of Appeal.

Of interest to patent applicants and patentees, the term 'plausibility' (and also the concept) is not used or applied by the German courts. Only in extreme cases of speculative patents or clearly non-plausible teachings (such as perpetual motion) do German courts consider this a bar to patentability. By contrast, the mere fact that a technical effect was speculation or not 'plausible' at the filing date does not lead to a presumption of invalidity in German patent law. If an initially speculated effect is proven to be correct by post-published data, the invention is retroactively proven to be 'usable'. Whether and, if so, on what grounds revocation or nullity can be raised in this case remains an open question. As a general rule, sufficiency of disclosure or enablement attacks play a much lesser role in German patent litigation and are rarely successful, again underscoring Germany's patentee- and therefore plaintiff-friendly patent litigation venue.

ENTITLEMENT TO PRIORITY (G 1/22 AND G 2/22)

In October 2023, the EBA also rendered its long-awaited G 1/22 and G 2/22 Ruling on formal priority. The decision is favourable for patentees and applicants, acknowledging a rebuttable presumption that applicants are entitled to claim priority and approving the so-called 'PCT Joint Applicants Approach'. The presumption was held to apply in any case where the priority applicant is not identical to the subsequent applicant, and regardless of whether the subsequent application is a PCT application. The cases underlying the G 1/22 and G 2/22 referrals concerned PCT applications (international applications) for which different applicants acted as applicants for different country designations and where only the applicants for one designation (US) were also the applicants for a priority-establishing application.

The board considered the joint filing of a PCT application by applicants for the US only, that are also applicants of an earlier application from which the PCT application claimed priority, and by further applicants for the other designated states. It found it to be an implied agreement that the priority claim should be valid for the PCT application unless a third party could substantiate substantial factual indications to the contrary. The German Federal Patent Court has already recognised the validity of the priority claim in similar situations, in the analogous German cases 4 Ni 8/20, 4 Ni 9/20, and Cinacalcet II.

COMMENT

Protecting innovation has never been more important. As businesses worldwide work in the face of the ongoing economic crisis, intellectual property – and in particular patents – continue to be invaluable assets in support of their company's strategy and success. Patent

owners can be confident that Germany will continue to be one of the top places in the world for protecting innovation and enforcing IP rights.

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Israel: A Deep Dive into National Prosecution Processes

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Summary

IN SUMMARY

This article provides an overview of patents in Israel, including requirements of patent applications and responses to them, examination of patents and enforcement of patents.

DISCUSSION POINTS

1. Details of the patent application process Oppositions and re-examinations
2. Invalidation and inter partes reviews
3. The examination process
4. Patent enforcement

REFERENCED IN THIS ARTICLE

1. Patents Law 5727-1976
2. Patent Examination Working Guidelines

FIVE KEY 'NEED TO KNOWS'

- Expedited examination is available in Israel.
- Section 18 of the Israeli Patents Law imposes certain disclosure requirements on applicants of patent applications.
- The Israeli Patents Law has limited grace period provisions, which exempt certain publications from the state of the art.
- Claims identity between two different applications is not accepted.
- A maximum of 50 claims are permitted under a basic filing fee.

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

ELIGIBILITY

In Israel it is only possible to obtain a Utility Patent. The Patents Law provides that almost any invention, whether a product or a process, in any field of technology is patentable if it:

1. is new and useful;
2. has industrial application; and
3. involves an inventive step.

However, procedures for therapeutic treatment on the human body are excluded by the Patents Law, as are new varieties of plants or animals, except microbiological organisms not derived from nature.

In addition, discoveries, scientific theories, mathematical formulae, rules for playing games and mental acts are considered as abstract ideas or processes that are devoid of technical characters. Notwithstanding this, such ideas or processes may be combined with additional technological means to result in products or processes in technological fields that are eligible for patent protection.

EXAMINATION TRENDS

Israel is an international search and examination authority. As well as Israeli entities, US and Georgian applicants may also use the Patent Office as an international search and examination authority.

The Patent Examination Working Guidelines are updated periodically and include strict guidelines relating to the examination of, among other things, antibodies, polymorphs, overlap, novelty of the target population and computer-related inventions. The guidelines (including English translation) can be found at https://www.gov.il/he/Departments/DynamicCollectors/work-procedure-db?skip=0.

Israeli examination tends to give weight to examination results in other jurisdictions. As a result, the use of procedures that allow examination or allowance to be expedited on the basis of results in another jurisdiction should be considered before initiating a substantive examination.

Section 13(a) of the Patents Law is strictly interpreted and actual support in working examples is generally required. Section 13(a) reads: 'The specifications shall end with a claim or claims that define the invention, on condition that each said claim reasonably arise out of the subject described in the specification.'

With respect to AI, the nature of future examination is unclear. While the Commissioner has decided that an AI cannot be a named inventor, their decision verbally excluded any discussion of the amount of human contribution to an invention that can render an AI-assisted development an eligible 'invention'.

An examiner's decision may be appealed to the Registrar of Patents. Decisions by the Patent Office, meanwhile, may be appealed to the court by the applicant or by a third party, if one is involved.

HANDLING OF OPPOSITIONS AND RE-EXAMINATIONS

In Israel there is a pre-grant opposition procedure. With regard to oppositions, the Patent Law provides that any person may oppose the grant of the patent within three months of the date on which the acceptance of the application is published. To do this they must file a written notice (with prescribed fees) to the Registrar of Patents. The grounds for opposition can include any one of the following:

1. there is a reason for which the registrar had the authority to refuse to accept the patent application;
2. the invention is not novel under section 4(2); or
3. the opponent and not the applicant is the owner of the invention.

A re-examination may be requested by the applicant after a Notification Prior to Allowance has been issued if new prior art comes up. The request to re-open examination must be filed

before the publication of allowance. Re-examination may also occur if the applicant asks to amend the allowed application or granted patent on its own initiative (for clarification, to remove obvious errors or to restrict the claims), either following an opposition against the published application, or following an application for revocation of the granted patent filed by a third party.

INVALIDATION AND INTER PARTES REVIEWS

A patentee may request the cancellation of a patent in their name. If this is granted, a third party may oppose the cancellation. Any person other than the patentee may apply to revoke or cancel a patent. Inter partes proceedings can last several years.

PATENT-TERM EXTENSIONS

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

1. a pharmaceutical product;
2. the process for manufacturing such a product;
3. the use of such a product;
4. a pharmaceutical preparation containing such a product;
5. a manufacturing process for pharmaceutical preparation containing such a product; or
6. a medical device that requires marketing authorisation in Israel.

It is important to note that strict deadlines apply from the date that regulatory approval is obtained.

PENDENCY LEVELS FOR THE LAST 12 MONTHS

According to the Annual Report of the Israeli Patent Office of 2022, the average time from the filing of an application until the end of examination is 39.5 months (compared to 41.8 in 2021). Different technological fields average different amounts of time, with examination of applications in biotechnology being the longest (on average 44.4 months from filing of the application) and mechanics, electronics and physics being the shortest (on average 37.2 months from the filing of the application).

EXPEDITED EXAMINATION

There are five different ways by which to achieve an expedited examination in Israel.

The first is to seek acceleration under section 19A of the Patents Law. Under this section, a petition for accelerated examination may be filed at the Patent Office on the following grounds:

1. likelihood of infringement;
2. advanced age or poor medical condition of the applicant;
3. public interest;
4. or unreasonably long delay in initiating examination by the IPO.

If the registrar is satisfied that the petition is well grounded, examination will commence as soon as possible, subject to payment of the prescribed fee. Accelerated examination is available for applications that were first filed in Israel. These provide a search report and a preliminary opinion on patentability well within 12 months of filing.

The second way to achieve an expedited examination in Israel is through filing a request for an accelerated examination under the Global Patent Prosecution highway programme with the Patent Office before substantive examination commences.

Third, applicants may also apply for preferential status for applications that relate to 'green' technologies such as preventing global warming, decreasing the contamination of air or water, and the like.

Fourth, modified examination may be granted under section 17(c) of the Law, on the basis of a corresponding patent having been granted in one of the following jurisdictions: Australia, Austria, Canada, Denmark, European Patent Office, Germany, Japan, Norway, the Russian Federation, Sweden, the United Kingdom and the United States.

According to the Annual Report of the Israeli Patent Office of 2022, the percent of applications granted under section 17(c) of the Law was 19.3 per cent (with similar percentages in preceding years).

Finally, applicants may accelerate examination by filing a response to the International Search Report/Written Opinion or to the Preliminary Examination Report, as long as this is done before the standard official Notification Prior to Examination is issued.

DUTY OF DISCLOSURE

Section 18 of the Patents Law imposes certain disclosure requirements on applicants. Prior to examination, the Patent Office will direct the applicant's attention to the need to submit information under section 18. This requirement is ongoing up to allowance of the application. The applicant is required to inform the office of any new references that are or have been cited (whether by patent offices or during various proceedings, such as oppositions, patent nullifications and other court proceedings) or that have surfaced in any other way, which may be of relevance in examining the issue of patentability. Great diligence is required in complying with this duty of disclosure requirements. Failure to disclose can be detrimental to the validity of a granted patent.

GRACE PERIOD

The Patents Law includes limited grace period provisions, which exempt certain publications from the state of the art. These include unlawful publication by a third party (section 6(1)) and, subject to prior notification to the Commissioner, display at a recognised exhibition (Section 6(2)) or publication by way of a lecture before a scientific society and also publication of proceedings of such scientific meeting (section 6(3)).

OVERLAP

Claims identity between two different applications is not accepted. For different applications filed by the same applicant on the same date, such as a parent and a divisional application, for example, partial overlapping between claims is accepted (eg, when the scope of protection in claims of the divisional application includes or is included in the scope of the claims of

the parent application). No claim overlap, even partial, is permitted for different applications filed on the same date by different applicants. Further details may be found in Appendix 5 of the Examination Guidelines.

ADDITIONAL FEES

The basic filing fee permits a maximum of 50 claims within an application. Any additional claim will attract an extra fee of 560 shekels. Furthermore, the basic fee permits a maximum of 100 description pages, excluding sequence listing pages. Every additional 50 pages will attract an extra fee of 273 shekels. A Small Entity Discount of 40 per cent on the official filing and acceptance fees is available to individuals and companies or partnerships with a turnover of less than 10 million shekels in the preceding year. This discount is not available for the national phase of a PCT application or for patent applications filed under the Paris Convention.

Specific Requirements

At a minimum, an application must include:

1. a specification including title by which the invention can be defined;
2. a description of the invention, with any drawings that may be necessary; and
3. a description of how the invention can be used.

The patent specification must end with a claim or claims that define the invention, provided that each claim is supported by the description.

The patent specification can be filed in in Hebrew, Arabic or English, although if it is filed in Arabic, the IPO will require a translation. Additional documents such as power of attorney, copy of priority document, translation and so on can be completed after filing.

Israel is a signatory to the Budapest Treaty. When an invention includes biological material that is not available to the public or it 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 and/or nucleic acid sequences are recited in the specification, a list of the sequences should be submitted in a computer readable form (.txt file). As of 1 July 2022, WIPO ST/26 is applied.

DIVISIONAL PATENT APPLICATIONS

The Patents Law allows for the filing of divisional patent applications. As long as the application has not already been accepted, the applicant is entitled to request that it be divided into one or more applications. Similarly, if the application includes more than one invention, then the registrar may direct the applicant to divide the application, as long as the application has not yet been accepted. Divisional applications can be further divided out of a pending divisional application before its acceptance. The date of each divisional patent application shall be the same as that of the application from which it was divided and it will enjoy same priority claim or claims.

There are no continuations or continuation-in-part applications in Israel.

PATENT OF ADDITION

If a patent holder is the owner of an invention which improves or modifies an invention for which a patent has already been granted, then they may request that a patent for the second invention be granted to them as a patent of addition. This patent does not need to involve an inventive step beyond the original patent. The patent of addition is effective for as long as the original patent is, and there is no need to pay any renewal fee with respect to the patent of addition on top of the fees paid for the original patent.

OFFICE ACTIONS AND PATENT EXAMINER INTERVIEWS

A response to an Official Notification should be filed within four months of its date of issue. Applicants are entitled to request an extension of up to four months for each round of examination. The total length of extension available for the entire process of examination is limited to 12 months.

It is possible to conduct an interview with the examiner. In this interview it is possible to discuss various aspects of the invention, its defects and possible corrections to overcome those defects. Interviews are scheduled directly with the examiner and should be accompanied by a written notification of the interview initiative, including details of the issues to be discussed. It should be noted that a request for an interview does not replace the duty to respond to a pending official notification.

If an examiner decides that examination has reached a dead end (usually but not always after two examination reports have been issued), a notification before formal refusal is issued. It is common and recommended to request an interview with the examiner when responding. There is no utility model or petty patent protection in Israel.

ADMINISTRATIVE ENFORCEMENT OF PATENTS

The Israel Patents Law deals with the state's right to exploit inventions. Section 104 prescribes that a Minister may permit the exploitation of an invention by government departments or by an enterprise or agency of the state, whether or not a patent for it has already been granted or applied for, if they find it necessary in the interests of national security or to the maintenance of essential supplies and services.

Furthermore, section 105 prescribes that the Minister may, if they find it necessary for the purposes enumerated in section 104, grant a permit under that section to a person who operates under contract with the state, in order to ensure or facilitate the implementation of that contract and for the requirements of the state only.

On 18 March 2020, for example, the Minister of Health issued a permit to the state to exploit an invention pursuant to these sections of the Law to import Kaletra (lopinavir 200mg/ritonavir 50mg) for the sole purpose of treating covid-19 patients. This authorisation was the first time that sections 104 and 105 of the Patents Law had been invoked for public non-commercial use.

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Specialist Chapter: EPO Opposition Procedures

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Dentons

Summary

IN SUMMARY

This article examines patent protection at the EPO and the process by which third parties can go through opposition.

DISCUSSION POINTS

- How do patent oppositions work?
- Oral proceedings
- Differences compared to national invalidity proceedings
- Recent changes to opposition practice
- Opposition strategy
- Additional benefits of the opposition procedure

REFERENCED IN THIS ARTICLE

- Revised Rule of the Boards of Appeal

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:

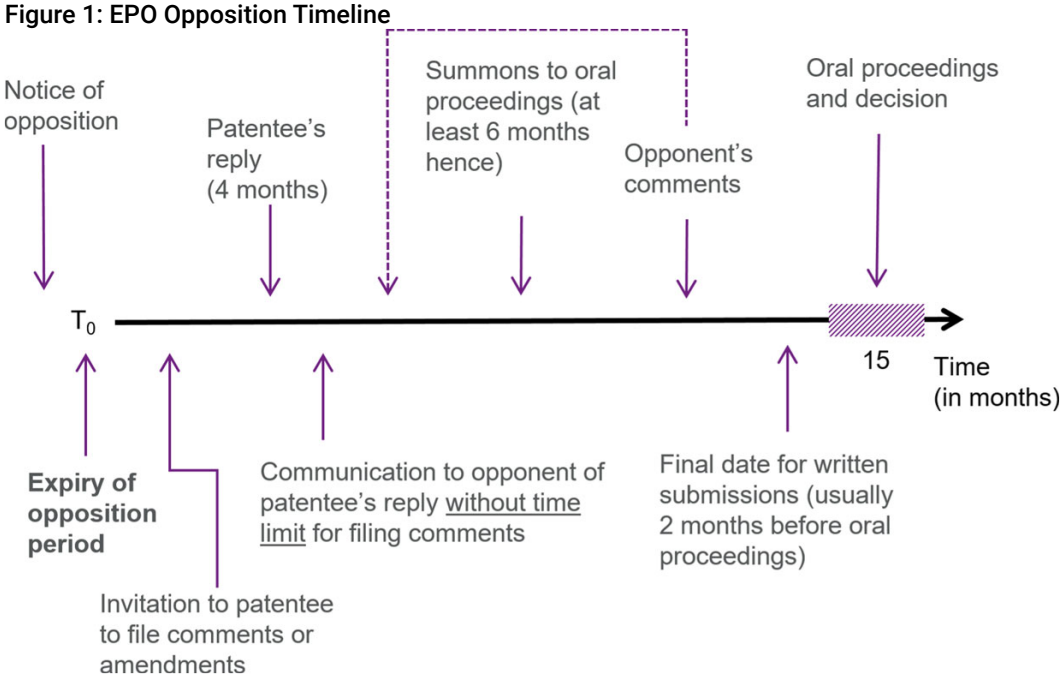
- a single opponent;
- no reliance on witness testimony or evidence of prior use;
- no extensive translation requirements; and
- using fewer than 10 primary prior art references.

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.

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:

Figure 1: EPO Opposition Timeline



- 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 per cent 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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Specialist Chapter: Patenting Computer-Implemented Inventions at the EPO

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Summary

IN SUMMARY

Computer implemented inventions are patentable at the EPO, but can often face significant resistance, in particular in relation to inventive step and, with increasing frequency, sufficiency. Case law on the assessment of computer implemented inventions can give the impression that prosecution of these cases involve different considerations from other inventions. We explain that the assessment of inventive step at the EPO for computer implemented inventions can be more clearly understood as a normal application of the well-known problem-and-solution approach, and highlight areas to be considered to avoid insufficiency objections.

DISCUSSION POINTS

1. Technical/non-technical subject matter
2. Inventive step
3. Computer-implemented inventions
4. Sufficiency

INTRODUCTION

Under the European Patent Convention (EPC), European patents should be granted for any inventions, in all fields of technology. At first glance this principle seems all-encompassing, similar perhaps to the US Supreme Court's phrase from the 80s in relation to the limits of patentability: "Everything under the sun made by man".

However, the European Patent Office (EPO) attaches great weight to the term 'technology', and from it imports a requirement that an invention must be 'technical' or have 'technical character'. The EPO's definition of technical also departs somewhat from the common-usage definition. Indeed, the EPO shies away from explicitly defining what is 'technical', although it does know what is not. The design of programs for computers is not considered by the EPO to be a technical pursuit, for example. Similarly, the devising of rules and methods for performing mental acts and mathematical methods, which often form the core of a computer program, is not a technical pursuit. In fact, the EPC is explicit that these things are not to be regarded as inventions.

That said, inventions implemented using computers are clearly patentable at the EPO. This is apparent from the large numbers of granted patents with claims that begin, "A computer-implemented method …". More specifically, if you can show that the computer-implemented idea provides an advance in a field of technology that is not limited to one of the excluded classes mentioned above, you can be granted a European patent.

INVENTIVE STEP

Practically, as is the case at other patent offices, two barriers must be overcome in order to patent a computer-implemented invention. First, the inherent patentability of an invention must be established. At the EPO, meeting this requirement is straightforward for a computer-implemented invention, since all that is required is that technical means be part of the claimed subject matter. Perhaps surprisingly, the use of a computer is considered

sufficient technical means – in other words, a program for a computer is, paradoxically, always inherently patentable due to the implied use of a computer!

As a consequence, most of the substantive assessment of patentability (and technicality) comes with the second barrier – inventive step. It is this barrier that causes most problems for computer-implemented inventions at the EPO.

Computer-implemented inventions come in many forms. They may relate to machine learning, simulations, graphical user interfaces, databases and so on. Specific case law on technicality has developed in each of these categories, and this vast corpus of decisions can give the impression that different types of computer-implemented invention involve different considerations. In fact, the assessment of inventive step at the EPO for any computer-implemented invention can be understood as a normal application of the well-known problem-and-solution approach. Although the issues that can occur may seem numerous, if these are considered during the initial drafting process then prosecution can be greatly simplified.

The problem-and-solution approach involves the identification of an objective technical problem that is solved by the novel features in the context of the closest prior art document. Because of the word 'technical' in the phrase 'objective technical problem', novel features that are deemed to be non-technical are disregarded in the analysis. Indeed, examination reports issued by EPO examiners frequently list large numbers of identified novel features but present them as struck-out to indicate that they will, in effect, be ignored when deciding whether the claim is inventive.

WHEN IS A NON-TECHNICAL FEATURE TECHNICAL?

The word technical is the cause of much confusion since it is not defined in the EPC. Indeed, at every opportunity, the Enlarged Board of Appeal of the EPO has intentionally not defined the term. This is because it is not apparent what fields of technology will arise in the future, and so a fixed definition of the term may not be sufficient to capture future advances in technology. As such, applicants do not have explicit guidance as to what features of computer-implemented inventions may be considered technical. On the other hand, the Boards of Appeal have confirmed that certain features, such as artificial intelligence models and details of computational simulations, are inherently non-technical.

However, there is a caveat. A feature initially deemed non-technical by the examiner can be argued to make a technical contribution to a claim if, by its combination with other technical features, it contributes to solving the objective technical problem. Such features can then be brought back into play when assessing inventive step.

This caveat is key to the patenting of computer implemented inventions. Put explicitly, the features of the computer-implemented invention are by definition merely software or mathematical in nature and so are, in essence, non-technical. However, their influence on some technical process can involve technical character. For example, a mathematical method for calculating a value is not a technical feature in and of itself. But if that value is a control parameter used for flying an aircraft more efficiently, the mathematical method can be said to have technical character by virtue of its interaction with the control of the aircraft, a clearly technical process.

In this example, the software influences a technical process that is external to the computer. However, technical character may also be based on the influence of a technical process

within a computer. This may be the case even if the purpose of the software being run is for an excluded application, such as a business method for insurance. A recent case (T2910/19) related to a computer-implemented method for calculating insurance losses incurred on properties following natural catastrophic events: a non-technical application. The calculations were carried out by parallel processing and the computer-implemented invention selected a processor based on the insurance-related functions already stored in the processors' local caches. This was considered to import technical character because it enabled the system to avoid the transmission of those functions to the local cache of a processor selected purely on the basis of conventional methods. As such, the technical steps of computation were achieved more efficiently and the method was found to be inventive.

Since the software features of computer-implemented inventions are, absent their context, to be considered non-technical such that they cannot contribute to the inventive merit of a claim, the key focus of argumentation about inventive step is often related to the effect of those features on the technical process. For example, consider an algorithm trained by machine learning that is being used to determine the optimum time to refuel a vehicle. If the algorithm enabled the vehicle to work more efficiently, then the algorithm might be patentable. However, if the algorithm simply optimised the monetary cost of refuelling, then this would not be a technical advance. Arguments as to the particular effect achieved by claim features are therefore common. Prosecution can be assisted by a clear explanation of the technical ramifications of the claim features in the description.

INVENTIVE ACROSS THE FULL SCOPE OF THE CLAIM

Other conventional aspects of the problem-and-solution approach can become relevant in relation to arguments about the technical effects of features. For instance, it is well explored that for a claim to have an inventive step at the EPO, it must be inventive across the full scope of the claim. That is, the objective technical problem must be solved by virtually all embodiments within the claim. For computer-implemented inventions, this can be brought out in several ways, each of them usually depending on the way the relevant features are expressed.

The requirement that a claim must be inventive across its full scope in effect means that the claim must be technical across its full scope. If it is possible to envisage, within the scope of the claim, both embodiments where the novel features have technical character and embodiments where the novel features do not have technical character, then the claim is not inventive. The most straightforward example of this is that a purely mental implementation of the novel features must be ruled out (that is, if the task could be carried out by a human, no matter how long it might take). If a claim covers a purely mental implementation, then it will encompass a non-technical mental act and so not be technical across its full scope. This is typically an issue with the way a claimed feature is expressed. However, it might be problematic if the patent specification was not drafted with the EPO in mind.

A more troubling example is that of a core advancement in AI – say a new and improved model architecture. If this architecture is claimed to apply to a particular technical problem, such as image enhancement, all is fine as the model may be said to contribute to solving an objective technical problem. However, the model may be much more widely applicable than that (it might also be great at financial analysis, say). A broader claim encompassing the financial analysis application would likely fail as now there is an embodiment where only non-technical problems are being solved. All of a sudden, the technical character imported into the new model vanishes, leaving non-patentable subject matter.

A further corollary of the requirement that a claim must be inventive across its full scope is that the technical effect relied upon must be necessarily achieved, as opposed to being a mere potential technical effect. A potential technical effect is a downstream effect in a technical process that is dependent upon certain conditions. An example is the use of a simulation to model a chemical process. The simulation may be useful in predicting an increased yield of a product. However, unless the claim is restricted in such a way that the increased yield is definitely achieved, it might not be possible to rely upon this effect to establish an inventive step.

IS THE TECHNICAL EFFECT ACHIEVED?

For a technical effect to be relied upon, it should be considered whether to limit the claim such that those conditions required for it to be achieved are recited as explicit limitations. In the case of a simulation, this may be achieved by (1) claiming the use of the simulation to solve a particular problem; (2) expressing the technical implementation that is specifically beneficial for the simulation; or (3) reciting a direct link with physical reality, such as explicitly claiming the sensing or control of a technical process.

When the inventive step relies upon the effect of novel software features on a technical process, care must be taken to ensure that those features actually influence the technical process as opposed to merely interact with it. As an example from case law (T1670/07), the use of technical means to send non-technical data does not imbue that data with technical character. However, data with some functional attribute beyond its information content may be technical.

Moreover, care must also be taken when a computer-implemented invention interacts with a user or operator. In many cases, technical character can be recognised in the use of software to assist a user in carrying out a technical task. For example, if the software presents information to the user that enables them to identify some otherwise non-observable parameter of a system – so that the user may better control the system, say – then it may be technical.

However, a technical effect must not rely on correct human decision-making. This is considered to break the chain of causality in achieving the technical effect. For example, if a computer program is provided to improve patient compliance with a drug regime, this could in some cases be recognised to have a technical effect. However, it is unlikely to do so if the improved compliance is conditional upon the correct behaviour of the patient.

The objective technical problem must be specific. It is not, for example, possible to simply recite in the claim non-specific, boiler-plate language such as “a computer-implemented method, used in a technical process, wherein ...”. It is necessary to limit the claim to the specific area in which the technical character is found. In the context of a computer-implemented invention that influences a technical process that exists outside the computer, it can therefore be beneficial to limit the claim to that specific process. For example, if the invention is the control of a manufacturing process, the claim might be limited either by reciting the manufacturing process itself or, alternatively, some feature that intrinsically links the computer-implemented invention to that manufacturing process.

The same limitation of the claim may be beneficial if the computer-implemented invention influences a technical process that exists within the computer. In one reported case (T2330/13), the invention defined novel process steps that in isolation would have been

non-technical but were specifically adapted for use with bit-strings and bit-matrices. Because these were positively recited in the claim, the alleged effect of efficient parallel evaluation was achieved.

COMPARISON WITH THE PRIOR ART

Of course, beyond the need for technical character, assessment of inventive step at the EPO always requires an identification of the technical effect achieved by the novel feature in comparison with the prior art. It is often the case with machine learning inventions that the technical achieved over the prior art is improved accuracy. Often the difference between a process for the estimation of a technical parameter by the claimed invention and by the prior art is the algorithm used for the estimation. In such cases, a technical effect should be recognised if the novel algorithm for estimation provides a more accurate value for that technical parameter.

However, beyond foreshadowing such improved accuracy, it is necessary to show that this improvement is achieved compared to the specific closest prior art cited by the examiner. If this prior art was not known to the applicant at the time of drafting, this may be problematic. Without evidence of the advantage, the objective technical problem may be defined as the mere selection of an alternative. In the context of machine learning, this can enable an examiner to argue that any machine learning algorithm may be simply substituted for the method of the prior art, and in the field of software there are rarely contraindications for such a substitution. Thus, it is important to establish an advantage over the prior art.

Interestingly, a similar situation often occurs in the field of chemistry, where it is common to file comparative data establishing that the purported advantage is achieved. This supporting evidence can be filed during prosecution to support arguments for patentability, as long as the technical effect is plausible from the originally filed specification. Although perhaps speculative, it is possible that a similar practice could arise in the field of machine learning.

SECONDARY INDICATIONS

The step of the problem-and-solution approach that requires the greatest care is typically the identification of the objective technical problem. Here, to avoid hindsight, it is important to remember that the problem that the skilled person is trying to solve in the prior art must not contain a 'pointer towards the solution'. This is an area in which computer-implemented inventions can be disadvantaged, since the case law has developed such that non-technical pointers to the solution can potentially form part of the objective technical problem, for example as a constraint to be met by the skilled person.

When arguing in support of an inventive step the issue of technical prejudice can often be used to show that a modification of the prior art would not have been made. In keeping with the limitation of the inventive step to technical matters, it is not possible to rely upon a non-technical prejudice in the prior art leading the skilled person away from the invention. Just because a diligent administrator or HR person would teach against the modification does not render it inventive. There has to be clear technical teaching in the prior art away from a particular modification (such as a perceived technical incompatibility) for a prejudice argument to be run in favour of an inventive step.

The relevant considerations for computer-implemented inventions in connection with inventive step therefore follow from the same analysis that is applied to other types of

invention. The main area of contention is whether it is possible to establish technical character for the various aspects of the claim under examination.

SUFFICIENCY

The consideration of sufficiency of disclosure is also the same for computer-implemented inventions as in other fields. However, in the field of AI and machine learning, this issue requires a little more attention to detail. In the case law (T161/18), some machine learning inventions have been found to be dependent, not only on the core algorithm used, but also on the selection and capture of training data. The same reasoning can be extended to other aspects, such as the choice of hyperparameters and basis functions. Many extra levels of detail can be provided for machine learning inventions, and they should not be routinely treated as a simple black box. Before drafting, there should be a comprehensive assessment of how all the aspects of the machine learning system contribute to its advantages.

While we are nowhere near a situation in which petabytes of exemplar training data need to be provided with every application, the requirement that the skilled person be able to carry out the invention based on the specification alone should nevertheless be taken seriously. In numerous cases this requires at least a discussion of how training data may be captured and what 'good' training data looks like. In some cases, the benefits of the machine learning invention might be robust to these details, and applicants must take care not to suggest that any of these details are essential to a technical effect that is to be relied upon for an inventive step. These issues should be explored in detail at the earliest stages and careful drafting with them in mind is crucial.

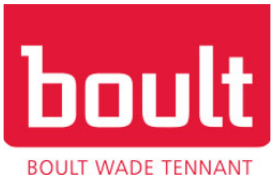
CONCLUSION

The task of patenting a computer implemented invention at the EPO can seem daunting given the long list of failed attempts reported in the case law and the seemingly complicated requirements. However, the patentability of computer-implemented inventions is certainly possible and is based on the same first principles as any other invention.

Moreover, as the EPO itself has recognised, AI and machine learning represent key driving forces in what may turn out to be the next technological revolution. Such techniques have already become ubiquitous in people's daily lives. For those innovating in these fields, strong and effective IP protection is essential. This often includes the need to obtain patents that not only survive first contact with the patent office but are also robust enough to stand up to post-grant challenge and subsequent litigation.

Given the large numbers of AI applications being filed every year the case law will likely develop at a rapid pace over the lifetime of applications filed now. Inevitably, decisions made on some of the difficult edge machine learning cases will bleed back into wider software patentability as a whole.

More than ever, it is important to be familiar with how these existing patentability principles relate to software inventions when drafting. Drafting is almost always the one chance to really 'get it right', and practitioners and applicants will have many years to live with the decisions made here. This is particularly true in the field of machine learning, where familiarity with the underlying algorithm is essential to ensure the best and most robust scope of protection is achieved.



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