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INTERNATIONAL FEDERATION OF  
INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION  
VON PATENTANWÄLTEN

## INFORMATION PAPER ON SCOPE AND IMPLICATION OF EXAMINATION GUIDELINES OR PATENT MANUALS ISSUED BY NATIONAL IP OFFICES

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In pursuance of the detailed discussion held in a workshop during the ExCo meeting in Zurich, it was realised that the examination guidelines or patent manuals issued by various national IP Offices had quite divergent scope and implication. In fact, it was ascertained during such discussion that some Patent Offices did not issue any guidelines at all. While the other Patent Offices did issue guidelines, they were not only binding on officials of the respective Patent Office but also on the applicants. Not only this, some Patent Offices issued guidelines unilaterally without consulting the stakeholders while others held extensive consultation and engagement with the stakeholders before finalising and issuing such guidelines. Some guidelines were challengeable in a court of law, while others were not. Such noticeable divergence in practice, content, process and legal implications of the guidelines or patent manuals issued by various Patent Offices prompted the group to take up a project to study the this topic in detail, prepare a report thereon and share it with the FICPI membership.

The first step towards achieving such a goal was to draft a questionnaire on the scope and implication of examination guidelines or patent manuals issued by various national IP Offices. Mr. Swarup Kumar volunteered to take initiative and in consultation with the Chair of CET 5, Mr. Francesco Paolo Vatti, CET 7 Chair, Mr. Kim Finilla and Mr. Danny Huntington, Member CET 5 and on the basis of inputs received from members of CET 5 and CET 7, such questionnaire was drafted and finalised. The questionnaire was then approved by the CET, ExCo and Bureau following which, such questionnaire was forwarded to the delegates of the national groups of FICPI for their input and comment. The best part is that detailed responses from 32 national groups : Argentina, Australia, Austria, Brazil, Belgium, Colombia, Switzerland, Chile, China, Germany, Denmark, Ecuador, Spain, Finland, Greece, India, Italy, Japan, Republic of Korea, Mexico, Malaysia, New Zealand, Netherland, Portugal, Poland, Romanian, Russia, Sweden, Singapore and South Africa, United States and Venezuela were received by us.

The responses are so divergent, insightful and enriching that putting them together in one document is indeed quite a task. Nonetheless, after extensive study and deliberation, an analysis of the responses received to each of nine questions posed to the respective national groups has been prepared and is presented hereafter for further study and possible action.

**Question 1 - Does your national IP Office (such as USPTO, JPO, Indian Patent Office (IPO), CIPO etc) issue guideline(s) or patent practice manual(s) for examination and processing of patent applications?**

From the responses received, it is noted that the majority of the national Patent Offices issue some form of guideline(s) or patent practice manual(s) for examination and processing of patent applications. The notable exceptions to this general rule are the South African, Romanian, Mexican, Greek, Ecuadorian, Netherlands, Venezuelan (not in use) and Belgian Patent Offices, who do not issue any specific guideline(s).

In accordance with Greek Law, the Greek Patent Office performs only a formal and not a substantive examination of patents, and thus, it does not issue guideline or patent practice manuals for



examination and processing of patent applications. The Mexican Examiners use their own criteria and expertise, but always base the procedures on the established laws, regulation and agreements.

**Question 2 - If the answer to Q1 is YES, please confirm whether there is only one all encompassing set of examination guidelines or manual issued by your IP Office, or in addition to the generic one, are there multiple guidelines issued for different fields of technologies? If there are multiple guidelines, please identify them individually with an identification as to the matter to which they refer (e.g. traditional knowledge, green technology, computer implemented invention, complementary examination of applications covered by PPH agreements etc.).**

The Argentinean, Austrian, Brazilian, German and Indian Patent Offices are ones who issue multiple guidelines. The Argentinean PTO has issued several guidelines, both general (all encompassing) and specific (for specific technologies). The German Patent Office issues separate guidelines for classification, search, examination, SPCs, and oppositions. Apart from a general Manual of Patent Office Practices and Procedure, which may be treated as a practical guide for effective prosecution of patent applications in India across all areas of technologies, the Indian Patent Office (IPO) issues multiple technology specific guidelines as well.

The Swiss, Chilean, Chinese, Danish, Spanish, US, Japanese, Finnish, Korean, Malaysian, Portuguese, Russian, Swedish, New Zealand, Colombian and Singaporean Patent Offices issue only a single all encompassing examination guideline or variants thereof. It is noticeable that the General Secretariat of the Andean Community issued an Andean Patent Manual in 2004, which is applicable to Ecuadorian IP Office as well.

In US, there is only one encompassing set of examining guidelines in the Manual of Patent Examining Procedure (MPEP); however, the manual contains separate chapters addressing specific technologies, such as biotech.

In China, there is only one all encompassing set of examination guidelines issued by SIPO. However, the Guidelines include a specific chapter for certain fields of technologies, such as, chemical and biotech field, computer program field, etc. Certainly, when needed SIPO might issue certain Commissioner's orders to amend some provisions in the Examination Guidelines to better fit practical needs. Similarly, in Japan, the Examination Guidelines and the Examination Handbook are applicable to all fields of technologies. The Examination Handbook has an annex that describes how the generic examination guidelines apply to different fields of technologies: computer software related inventions, biological inventions, and medicinal inventions. The Korean Patent Office (KIPO) also issues a general patent examination Guideline. However, the ninth chapter of the said Guidelines for Patent Examination explains the detailed standards for inventions related to biotechnology, medicines-cosmetics, foods, functional drinking water, organic-inorganic compounds, alloys, polymer, textile industry, architectural design, and computer.

There are two documents of the Polish Patent Office which have a character corresponding with the role of guidelines or patent practice manual: 1) *"The Directives of the President of the Polish Patent Office Regarding the Interpretation of Selected Provisions of the Act of 30 June 2000 - Industrial Property Law"*; and 2) Publication entitled *"The Inventor's Guide"* (most recent edition – 3<sup>rd</sup> edition published in 2017).

While the New Zealand Patent Office has issued a single guideline, due to the Patents Act 2013 only relatively recently coming into force, the associated examination guidelines are still under



development and so are not all encompassing. The guidelines are structured in relation to the respective sections of the Act. Some of those sections address issues to specific fields of technology.

**Question 3 - If the answer to Q1 is YES, please confirm**

***(i) whether your IP Office publishes the draft guidelines for review by the stakeholders and asks for their comments on such drafts or do they publish only the final version thereof unilaterally?***

***Also, if comments are asked for :***

***(ii) does your IP Office provide the stakeholders sufficient time for review of the draft and submission of comments?***

The Japanese, Indian, Chinese, Korean, Brazilian, US and Singaporean Patent Offices publish the draft guidelines for review by the stakeholders and ask for their comments on such drafts. They also generally provide reasonable time to review such guidelines.

Japanese Patent Office (JPO) publishes draft guidelines and asks for public comments. JPO provides sufficient time for review of the published guidelines. The Indian Patent Office (IPO) as well publishes the draft guidelines and invites comments from the stakeholders. However, the only exception to the practice has been “Guidelines for Processing of Patent Applications relating to Traditional Knowledge and Biological Material”, which was published as a final draft by the IPO in November 2012. The IPO usually provides sufficient time for providing comments on the draft guidelines. Similarly, the Korean Patent Office (KIPO) also drafts and publishes a draft version of the patent examination guidelines, and requests comments from stakeholders (KIPO Examiners, Korean Patent Attorneys Association, etc). The KIPO provides sufficient time for review and submission of the draft.

Chinese Patent Office (SIPO) also publishes the draft guidelines for review by the stakeholders and asks for their comments on such drafts. According to past experience, SIPO usually provides the stakeholders one month’s time for reviewing the draft and submission of comments. IPOS Singapore publishes the draft guidelines for review by the stakeholders and asks for their comments on such drafts. IPOS provides the stakeholders with time for review of the draft and submission of comments. In general, four weeks are provided for submitting comments on such drafts. This period can be extended upon written request by a stakeholder.

Generally the USPTO publishes proposed changes to the MPEP in the form of a public memo and in response to which comments are received from the stakeholders.

The Australian Patent Office asks for comments from stakeholders directly, such as from FICPI AU, and also via the consultation groups that FICPI AU participates in. Generally sufficient time is provided, but sometimes not. A lot of the time, it depends on what are the external constraints on the office.

On the other hand, the draft guidelines are not published for review by stake holders by Argentinean, Chilean, German, Danish, Finnish, Greek, Portuguese, Russian and Swedish Patent Offices.

Certain unique cases have also been encountered with respect to the Spanish, Swiss, New Zealand, and Malaysian Patent Offices. Only the final version is published by the Spanish Patent Office. However, they are open to consider observations from users afterwards.



The draft guidelines for review by the stakeholders are not published by the Malaysian Patent Office (MyIPO). But MyIPO does have annual and regular dialogues with the stakeholders where issues relating to the Guidelines may be raised and discussed. Practice directions may be issued by MyIPO from time to time to clarify any identified ambiguity or uncertainty in any aspect of the patenting process.

For the New Zealand Patent Office (IPONZ), the practice has varied over time. Under the previous Patents Act, and particularly during the 2000's, draft guidelines were released for review by stakeholders. Under the new Act examination guidelines are now implemented without a general exposure to stakeholders of a draft version of intended changes to the examination guidelines. However, there are Patent Technical Focus Group meetings between IPONZ and a handful of people from the profession which allow for the consideration of intended changes but in most instances there is no or little time to consider draft guidelines before they are implemented by IPONZ. Despite the low level of review by stakeholders of draft guidelines, IPONZ is nonetheless proactive in getting feedback from stakeholders regarding possible legislative changes.

The IPI (Swiss Federal Institute of Intellectual Property) does not publish draft guidelines for review by the stakeholders. However, the IPI consulted the stakeholders in recent years when a major revision of the SPC examination was planned. The stakeholders were invited to participate in round table discussions and to file written comments on proposed changes in the examination practice.

**Question 4 - If the answer to Q3 (i) is YES, please confirm**

***(i) whether while drafting the guidelines, the stakeholders are involved more deeply through consultation, discussion and/or invitation to drafting and review sessions? In other words, is a consultative approach used by your IP Office?***

The Indian, Korean, Chinese and Australian Patent Offices involve the stakeholders more deeply through consultation, discussion and/or invitation to drafting and review sessions.

The Indian Patent Office (IPO) follows a consultative approach for framing guidelines for examination of patent applications in specific fields of technologies. The general procedure followed at the IPO is as follows:

(a) A draft of the examination guidelines is first published by the IPO and a public notice by the Office of the Controller General of Patents, Designs, and Trademarks (the 'Controller General') is issued inviting comments/suggestions from the stakeholders within a stipulated time period.

(b) The Controller General and a group of assigned Joint Controllers/Examiners internally study the comments/suggestions received from the stakeholders and arrive at their assessment. If found reasonable, the inputs are suitably incorporated into the guidelines and thereafter finalized and published.

(c) One or more stakeholders meeting may also be held with the Controller General and if required, with the chairman of the Department of the Industrial Policy and promotion and, the Ministry of Commerce and Industry.

(d) If the suggestions are found reasonably in agreement with the revised guidelines, the same are incorporated into the guidelines and are thereafter published as final guidelines indicating the date of effect of the guidelines.



However, the guidelines may always include a disclaimer *“The guidelines are subject to revision from time to time based on interpretations by a court of law, statutory amendments and valuable inputs from the stakeholders”*. Thus, the guidelines, in effect, do not constitute rulemaking under the provisions of the Patents Act, 1970 and the rules made thereunder. Also, they are subject to further improvements based on inputs received from the stakeholders, if such demand arises from a majority of stakeholders.

While drafting the guidelines, a consultative approach may be used by SIPO. Specifically, if SIPO is planning to amend certain part of the guidelines, SIPO may invite the stakeholders to have discussion or provide written opinions on how to amend the guidelines.

The stakeholders are involved through consultation and discussion when JPO drafts and reviews the guidelines. JPO invites the stakeholders to advisory councils to discuss any issues in the current guidelines and ask for any revisions necessary in the future.

The KIPO drafts a guideline and receives written comments (sometimes by discussion) from stakeholders. The following procedure is followed:

- (a) The KIPO sets the deadline and collects stakeholders’ opinions as to whether there are items of which revision is required on the guideline.
- (b) The KIPO drafts guidelines and requests stakeholder comments on draft guidelines.
- (c) The KIPO publishes final guidelines reflecting stakeholder comments.

In US, typically Notice of the memo published in the Federal Register. In a recent memo published in April, the public was given 4 months to comment. While the USPTO holds “roundtable discussion” to meet with the public and receive input on various issues, the formal process for revisions to the MPEP is not an iterative process. Rather the USPTO publishes the proposed changes, receives comments (which they presumably consider) and the final revisions are made some time there after.

When the first draft is ready, the Brazilian PTO publishes it and establishes a period for public consultation. During this period, the stakeholders may file comments and suggestions through a specific form, indicating the proposed amendments and the respective justifications. By the end of the public consultation, the BRPTO analyses all submissions and then issues the final version of the guidelines. The BR PTO sometimes calls a meeting with the Brazilian Association of Industrial Property (ABPI) for announcing that the drafting of internal regulations will be initiated. At that occasion, the BR PTO briefly discusses the subject with the ABPI and listens to their considerations.

The Australian Patent Office conducts consultation groups for patents, trade marks and designs, and FICPI AU has representation at each of these meetings. This is considered a very good approach, where FICPI AU can raise issues, and receive briefings on matters in the pipeline and act as a sounding board to the office. Very formal consultation group meetings are held 3 or 4 times a year, which are chaired by a senior policy person of the Office and will generally involve attendance by the Commissioner/Registrar, Deputy Commissioner/Deputy Registrar, and senior personnel within the Office in charge of a particular project. The meetings have a detailed agenda and minutes, and action list. The stakeholders include FICPI AU, the Institute of Patent and Trade Marks Attorneys of Australia and New Zealand, the Law Society and the Australian Manufacturers/Inventors Association. Trade Marks and Designs are combined in the one meeting, and patents has its own meeting. There



is a separate group called the IP Professional Forum, on which FICPI AU also sits, which has a wider stakeholder group attending. These meetings provide a higher-level policy overview of everything that IP Australia is doing. These meetings are attended by the Director General and the Commissioner and Registrars.

The Patent Department of the Swedish Patent Office twice a year has consultation meetings with representatives from both the free profession and industry for discussion of practical matters, as well as policy matters. In some of these consultation meetings questions are discussed, regarding proposed amendments to the guidelines, and also the representatives ask for amendments which may be confirmed by amendment of the guidelines. FICPI Sweden is represented on the consultation meetings.

Technical Focus Group meetings occur between New Zealand Patent Office (IPONZ) and a handful of people from the profession which allow for the consideration of intended changes. Patents TFG meetings have been sporadic over recent years with only at least one meeting per year, however IPONZ has indicated to having three meetings a year going forward. There has been a tendency in the recent meeting that IPONZ is attempting to be more consultative and receptive to discuss more fully proposed guidelines. The procedure going forward is to involve providing members of the Patents TFG with the draft guidelines for review and discussion before the guidelines are implemented (instead of the old procedure which in most cases was here are the guidelines that have been implemented).

The rest of the Patent Offices either do not have such a consultative approach or do not have Patent Manuals at all.

***Question 5 - If the answer to Q1 and/or Q4 is/are YES, please confirm whether your IP Office is generally appreciative of the submissions made by stakeholders and whether they are amenable to amend the guidelines, if needs be, or do they adopt a rigid approach and tend to finalise the guidelines without considering the views expressed by the stakeholders? If your IP Office is amenable to amendments post consultation, can you, from your experience, give one or more examples of such approach adopted by your national IP Office?***

The Australian, Chinese (SIPO), Spanish, Indian (IPO), Korean (KIPO), Malaysian, Brazilian, New Zealand and Swedish Patent Offices are generally appreciative of the submissions made by stakeholders.

The Australian Patent Office is very appreciative of submissions made especially by FICPI AU to ensure that they do not make a major slip-up. For example, FICPI AU will always be provided with an exposure draft of proposed legislative amendments to some IP act.

SIPO is generally appreciative of the submissions made by stakeholders and, they are amenable to amend the guidelines, if needs be. The guidelines were amended in April 2017, giving more freedom for the applicant to draft the claims for a software related invention. As the old guidelines have strict requirement on the examination of the software related invention, many industries and patent attorneys raised voice for amending the related part of the guidelines to give reasonable protection for the software related invention. SIPO fully took the same into consideration, and as of April 1 of this year, the relative provision in the Examination Guidelines of SIPO is much more user friendly, i.e. the applicant has many more ways to draft claims covering the software related invention.

The submissions of the stakeholders are duly considered by the Indian Patent Office (IPO) for making revisions in the draft guidelines. The guidelines on examination of patent applications in the filed of



pharmaceuticals were revised after receiving comments from stakeholders and a meeting conducted in relation to same. For example, the original draft of the guidelines mandated the applicant to provide the INN name of the drug, to be claimed in the application. The same direction was obliterated after the objection from the stakeholders. The making of the draft guidelines for the examination of the CRI is another such example which underwent similar amendments post criticism by the stakeholders. A timeline of the making of the CRI guidelines briefing the procedure adopted by the IPO is given below:

(a) A draft version of the computer-related inventions (CRI) guidelines was first published by the IPO on June 28, 2013.

(b) The IPO consulted various stakeholders and considered their feedback. The final guidelines were published on August 21, 2015. This version was more liberal than the draft version.

(c) However, the final guidelines were put in abeyance using a public notice on December 14, 2015, without clearly specifying reasons for the changes. It was speculated that a few software companies strongly opposed the guidelines as published on August 21, 2015, and led a group of civil society organizations, academicians and start-ups in writing a joint letter to the Prime Minister's Office, the concerned ministries and the Patent Office requesting to recall the Guidelines.

(d) A revised set of guidelines considered more restrictive than the previous set was issued on February 19, 2016. A three-step test was adopted to examine CRI applications where the third step required examiners to outright reject the claim of a patent application if the claimed invention did not possess any novel hardware.

(e) Aggrieved by the restrictive terms, stakeholders made requests to the Department of Industrial Policy and Promotion (DIPP) and the IPO to reconsider the revised guidelines.

(f) The latest version was issued on June 30, 2017, and marks a return to the liberal approach. This version is based on the recommendations of an expert committee established by the DIPP. The committee examined various representations and held intensive stakeholder consultations in order to consider a diverse range of views.

JPO is generally appreciative of the submissions made by the stakeholders and reflects upon their opinions when revising the guidelines. JPO once issued a new guideline for examining product-by-process claims after the Supreme Court decision and JPO received feedback and opinions from industries and attorneys and revised the new guideline a couple of times to reflect the opinions.

The KIPO is generally appreciative of the submissions made by stakeholders and they are amenable to amend the guidelines if needs be. The KIPO can revise its guidelines if it needs to reflect stakeholder feedback.

The Brazilian PTO is generally appreciative of the submissions made by stakeholders, and is amenable to amend the guidelines. More frequently, the BR PTO adds amendments, when the submissions indicate that the wording of the guidelines is unclear and/or may lead to a misinterpretation. Usually, no relevant amendments on substantive aspects are added to the guidelines after the consultation.

Malaysian Patent Office (MyIPO) actively seeks feedback, questions, comments and submissions from the stakeholders e.g. the various IP associations presenting the IP practitioners such as the



Malaysian IP Association of Malaysia and IP Committee of the Malaysian Bar Council. Practice Directions in the form of Patent Notices have been published at MyIPO's website to clarify some of the concerns of the stakeholders.

In general, New Zealand Patent Office (IPONZ) is amenable to amendment of proposed guidelines following their discussion at Patent Technical Focus Group (TFG) meetings. However, in the past, they have taken a rigid approach on particular topics without considering the views of the members of the Patents TFG. It is hopeful that in the future IPONZ will be more amenable and flexible to the views of the members of the TFG before any draft guidelines are implemented and IPONZ have indicated that they are willing to consider any amendments to the guidelines post implementation of the guidelines.

The Swiss Patent Office (IPI) is generally appreciative of the submissions made by stakeholders. However, stakeholders very rarely make a submission to amend the guidelines, and that the IPI would only be amenable to amendments in case of clear necessity.

With regard to the guidelines, there is no concrete interaction with the German Patent Office, however the office is in continued discussion with the stakeholders (annual official meeting with stakeholders plus annual working meeting with the Kammer; the main drafting work (apart from the guidelines for examination) is done by the ministry though, the stakeholders always have a possibility of commenting.

Representatives of Danish national patent office meet regularly with stakeholders and are generally appreciative of submissions and suggestions for amendments.

The Finnish IP Office has indicated that it is appreciative regarding feedback of the content of the manual and suggestions on new topics. However, at the present moment, no examples of such approach are available.

With regard to the Manual, the Portuguese Office tends to finalise it without considering views expressed by the stakeholders. However, in a recent project for amending the Industrial Property Code, stakeholders participated in commenting on a first draft provided by the Office. Thus, a possible change of practice may be identified.

No case where such an amendment has been suggested by practitioners in Singapore is imminent. Also, IPOS changing its position on anything based on feedback received from the stakeholders is unheard of. However, in view of recent interaction with a group of IP attorneys, IPOS has put the introduction of a formal procedure for auxiliary requests on hold.

***Question 6 - If the answer to Q1 is YES, do the guidelines have the force of law, i.e., are such guidelines binding in nature for***

***(a) the IP Office officials***

***OR (b) the applicants and other interested parties***

***OR (c) both?***

Besides China, where the Examination Guidelines issued by the SIPO are binding in nature for the IP officials, the applicants as well as the other interested parties, there is no other country, which applies this rule unequivocally.





For most Patent Offices, the Examination Guidelines are non-binding and do not have force of law. For instance, the KIPO's patent examination guidelines do not have the force of law. From New Zealand Patent Office's perspective, the guidelines have no force of law for any party. Any questions of law are primarily resolved with reference to the legislation. Where there is any inconsistency between the guidelines and the legislation, it is the legislation which prevails.

With respect to some Patent Offices, the Guidelines are followed by the officials of the Patent Office as a matter of practice, administrative direction or as reference material. For instance, for the Argentinean Patent Office, the Guidelines do not have the force of law, but in actual practice, they are binding on the PTO's officials. Similarly, the guidelines issued by Swiss Patent Office are legally not binding for third parties. However, such guidelines are binding directives or administrative regulations for members of the IPI. From Indian Patent Office's perspective, the guidelines are not binding. However, in practice, they are routinely relied upon by the officials of the IPO, more so, from the perspective of applying a uniform practice before different branches. The Manual does not have the force of law for officials or other parties in Portugal, but does provide an expectable practice of the Office.

Section 1.A.1.2. of the current Singapore Patent Examination Guidelines seem to merely declare them as a training tool: "The Guidelines aims to provide the Examiner with a better understanding to the application of the Patents Act and Rules during the course of their work." However, one can safely assume that a SG Patent Examiner would in case of doubt follow these Patent Examination Guidelines.

The Guidelines are considered binding on US Examiners, but not on courts. The Guidelines can and do get overturned by the US courts, particularly the CAFC or SCOTUS. The Guidelines are binding on applicants and other interested parties.

***Question 7 - Is there an exception to the legal principle that if the Guidelines of the IP Office are inconsistent with the Patent Act (statute) of your country or Rules thereunder, the statute invariably prevails? If so, please give one or more examples.***

Interestingly enough, there does not appear to be any express exception to the legal principle that if the Guidelines of the IP Office are inconsistent with the Patent Act (statute) of a country or Rules thereunder, the statute invariably prevails. In most cases, as pointed out by the Spanish group, the normative hierarchy always applies. That is to say that the Patent law cannot be contradicted by the implementing regulations, and the law or any rules or regulations thereunder cannot be contradicted by the office guidelines. Also, a Court decision may overrule the requisite contradictory part of the guidelines.

Under the Swedish system, there is as such no exception to the said legal principle but in practice deviations from the statutes many times occur for practical reasons. E.g. in accordance with the statutes every applicant/patentee has to sign a Power of Attorney, if someone else is to represent before the Patent Office. However, for validating European patents, after a suggestion from FICPI Sweden, the office has decided not to require the filing of a Power of Attorney for a party filing the Swedish translation.

***Question 8- If the guidelines are found to be contrary to the IP statute or established precedent of your country, are they challengeable in a court of law? If so, are courts amenable to putting things into perspective in light of legal provisions? Please give one or more examples, if any.***



There are many countries where the guidelines which are found to be contrary to the IP statute or established precedence can be challenged. For instance, in Argentina, if the guidelines as a whole, or a specific provision in them, are found to be contrary to any other norm of a higher hierarchy (constitution, treaty, statute) then they must be held to be invalid. As a matter of fact the 2003 Guidelines have been challenged in Court as being inconsistent with the Constitution and the Patent Law; a decision is still pending. Along similar lines, guidelines may be challenged in Singapore as well. In fact, In light of the Singapore Court of Appeal decision of *Warner-Lambert Company LLC v Novartis (Singapore) Pte Ltd [2017] SGCA 45*, Chapter 7, Section E of the Guidelines have been updated to provide clarity on the assessment of post-grant amendments, including the issue of “obviously invalid” claims at paragraphs 61 to 65 of the Court of Appeal decision.

Similarly, in Spain and Denmark, the guidelines may be challenged. In fact, in Denmark, the guidelines may be challenged either before the Board of Appeal of Patents and Trademarks or before the courts of law. In India, the Indian Patent Office (IPO) issues the guidelines for examination of patent applications in exercise of its administrative authority. Therefore, the same can be challenged in court of law in at least a writ petition. However, there is no precedence of such challenge in India, to date. Similarly, the Guidelines may be challenged in Court and under the Malaysian legal system, the Courts are free to review the validity of the Guidelines. There are, however, no examples of such instances.

In US, the guidelines may be challenged in court. They may be challenged either indirectly through an inter partes litigation or directly in an ex parte appeal proceeding.

In Japan, the guidelines are challengeable in a court of law. IP High Court and Supreme Court can revisit the guidelines issued by JPO in light of the IP Statute and reverse the guidelines. The court decision forces JPO to revise the guidelines. JPO sometimes quotes the court decision in the revised guidelines as a reason for revision. The most recent example is the examination of product-by-process claims. Similarly, consisting of a set of opinions and good practices as defined by the Portuguese IP Office, and as referred, the Manual does not have force of law, and therefore is challengeable before a court, as any other practice of the Office.

In New Zealand, since, the guidelines have no force of law, they can be challenged in a court of law or even by way of a tribunal hearing that results in a Commissioner’s decision. Although not under the current Act, in *Bomac Research Ltd v Merial Ltd, HC CIV-2009-485-2141*, 14 April 2010, the question arose as to whether an applicant for an extension of time should be required to file reasons for the application. The guidelines published on the IPONZ website required an applicant for an extension of time to give “full and detailed reasons for the request” and to “convince the Commissioner that the extension of time is justified”. The High Court rejected the submission that it was incumbent upon the applicant to prove both the need for the extension and diligence in attempting to meet the current deadline. The High Court ruled that the guidelines, while no doubt useful, cannot be applied prescriptively and cannot be used to modify the legislatively provided unfettered discretion.

On the other hand, neither the Russian PTO nor courts use the guidelines as a legal basis for their decisions. The guidelines are neither binding in nature for the Russian PTO nor for the other stakeholders, and they cannot be challenged in a court.

Some countries have a legal position which is somewhere in between the two far ends described above. For instance, in Switzerland, IPI decisions based on the guidelines are challengeable at the



Federal Administrative Court (by a party involved in the proceedings, e.g. the applicant/proprietor or opponent). The guidelines *per se* can not be challenged in court.

Similarly, in Chile, as the guidelines are only a compilation of the criteria generally applied by the PTO in patent prosecution, which do not constitute and will not constitute a part of the IP statute, it shall not be necessary to change them. But if a resolution or an opinion is based on the guidelines, it shall always be possible to challenge such a resolution or opinion at any time and in any state of the prosecution, including in a court of law. The Chilean Courts will always decide based on law and/or Law Regulation Rules.

In China, if the guidelines are found to be contrary to the IP statute or established precedent in China, someone may file a law suit with the court based on any specific decisions made by SIPO or Patent re-examination Board. Under such a situation, the court will examine whether the Guidelines applied by SIPO or Patent re-examination Board in the decision are contrary to the IP statute or established precedent. If it is found that the Guidelines applied by SIPO or Patent re-examination Board are contrary to the IP status or established precedent, the court may make a judgment revoking the decision made by SIPO or Patent re-examination Board by referring to the IP statute or established precedent directly, and the inconsistent provision in the Guidelines would not be taken into consideration by the court. But the court usually will not explicitly mention in the judgment that the Guidelines are illegal for being inconsistent with the IP statute or established precedent.

In Korea, if the KIPO's patent examination guidelines are found to be contrary to any statute or established precedence of the country, they may be brought to court. However, the court cannot modify the patent examination guidelines in light of the legal provisions. The KIPO can though voluntarily modify the patent examination guidelines in accordance with the court's ruling. In 2014, the Supreme Court said that the double numerical limitation including the expression such as 'preferably' is clear, but the KIPO has yet disclosed such double numerical limitation as an unclear description in the patent examination guidelines.

In Sweden, probably it would not be possible to challenge the guidelines in court, but if the result of the guidelines would lead to that a rejection (or grant) is appealed to the Patent and Market Court, another decision there could force the Patent Office to amend the guidelines.