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OPPOSITION SYSTEMS

Document prepared by the Secretariat

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EXECUTIVE SUMMARY

- 1. Pursuant to the decision of the Standing Committee on the Law of Patents (SCP) at its thirteenth session, held from March 23 to 27, 2009, in Geneva, The present document is a preliminary study on patent opposition systems (document SCP/14/5) which was prepared by the Secretariat. That document addresses patent opposition systems. It contextualizeds various aspects relating to existing opposition systems in a comprehensive manner, and containeds no conclusions.
- 2. At its sixteenth session, held from May 16 to 20, 2011, in Geneva, the SCP requested the Secretariat to revise document SCP/14/5, taking into account the comments made, and any additional information to be submitted, by Member States. The present document implements the above request and revises the document on issues which were raised by Member States at the fourteenth, fifteenth and sixteenth sessions of the SCP, taking into account information submitted by Member States regarding their opposition systems.
- 3. Following a general introduction, Chapter II provides an overview of opposition systems as they exist in many countries. While illustrating that national opposition systems vary from one country to the other, it describes general characteristics of the opposition systems in patent proceedings.
- 4. Chapter III describes the objectives of opposition systems and their role in the proper functioning of the patent system. Costs and benefits are <u>mainly</u> described from the viewpoint of quality and validity of patents, as well as of efficiency and effectiveness of patent procedures <u>so</u> that opposition systems support the public policy objectives of each country.
- 5. Chapter IV looks specifically into international agreements. While no international treaty regulates patent opposition systems *per se*, some provisions relating to procedural aspects in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Patent Law Treaty (PLT) may also be applicable to opposition procedures.
- 6. Chapter V describes the national/regional laws and practices of <u>Australia</u>, Brazil, <u>Denmark</u>, Egypt, <u>Finland</u>, <u>Germany</u>, <u>Honduras</u>, India, <u>Pakistan</u>, <u>Portugal</u>, <u>the Republic of Moldova</u>, <u>Spain</u>, <u>Sweden</u>, the European Patent Office (EPO) and the Eurasian Patent Office (EAPO) as concrete examples of different opposition systems.
- 7. Chapter VI finally provides some other mechanisms that are related to opposition systems, namely, re-examination systems applied in Australia, Denmark and the United States of America some countries and third party observations mechanisms available in Australia, Denmark, China, Finland, Japan, Mexico, Pakistan, the Philippines, Slovak Republic, the United Kingdom and the United States of America. They are not opposition systems stricto sensu. However, with respect to the shared objective of increasing the quality of granted patents by taking into account the wider knowledge of the general public, they are included in this document with a view to providing supplementary information.

I. INTRODUCTION

- 8. At its thirteenth session which was held from March 23 to 27, 2009, in Geneva, the Standing Committee on the Law of Patents (SCP) asked the WIPO Secretariat to establish, for the next session of the SCP, preliminary studies on two additional issues, namely, transfer of technology and opposition systems.
- 9. It <u>wasis</u> understood by the Committee that <u>these those</u> issues <u>are were</u> not to be considered prioritized over other issues contained on the list which was established during the twelfth and thirteenth sessions of the SCP and was contained in the Annex to document SCP/13/7 (see paragraph 8(c) of document SCP/12/4 Rev.).
- 10. Accordingly, this document <u>SCP/14/5 has beenwas</u> prepared by the Secretariat as a preliminary study on the issue of opposition systems for the fourteenth session of the SCP, to be held from January 25 to 29, 2010.
- 11. At its sixteenth session, held from May 16 to 20, 2011, in Geneva, the SCP requested the Secretariat to revise the preliminary study on opposition systems (document SCP/14/5), taking into account the comments made, and any additional information to be submitted, by Member States. The present document implements the above request and revises the document on issues which were raised by Member States at the fourteenth, fifteenth and sixteenth sessions of the SCP, taking into account information submitted by Member States regarding their opposition systems.¹
- 12. The present document primarily addresses traditional opposition systems, which are understood as time-bound inter partes procedures before a patent office, under which an opponent challenges the patentability of inventions and the applicant (or the patentee) is given an opportunity for rebuttal. However, with respect to the shared objective of increasing the quality of granted patents by taking into account the wider knowledge of the general public, related mechanisms, such as re-examination systems and mechanisms that allow third parties to submit prior art information to a patent office, are also briefly described in Chapter VI.
- 13. It is probable, however, that the term "opposition system" may have different meanings under various national laws or in different languages. Thus, in addition to the information on opposition systems in the above sense, Member States have submitted information on various procedures available under the national laws including, for example, on invalidation or revocation procedures conducted before the patent offices/quasi-judicial bodies and/or courts and procedures related to the limitation of granted patents which may be initiated solely by the patentee. Although those procedures also aim at improving the quality of granted patents, they were not included in this document, since the purpose of the preliminary study is to focus on time-bound inter partes opposition systems generally filed by third parties and related mechanisms, such as re-examination procedures and third party observation mechanisms conducted before the patent offices. However, the submissions containing those other procedures are available on the website of the SCP electronic forum, in view of their valuable contribution to the better understanding of national systems.

In response to Circular 7992 dated June 10, 2011, the information has been received from

Australia, Denmark, Finland, Georgia, Germany, Honduras, Mexico, Pakistan, Portugal, Republic of Korea, Republic of Moldova, Slovak Republic, Spain, Sweden, Ukraine, the United States of America and the European Patent Office (EPO).

Information on those other procedures was received from Costa Rica, Mexico, the Republic of Korea and the Slovak Republic.

14. At the twelfth session of the SCP, it was clarified that the *modus operandi* of the Committee, namely, to move forward along a number of tracks, including the preparation of preliminary studies, was agreed upon for the purpose of developing a work program of the SCP (see paragraph 123 of document SCP/12/5 Prov.). In view of this specific background, this preliminary study contextualizes various issues relating to opposition systems in a holistic manner, and contains no conclusions.

II. OVERVIEW OF OPPOSITION SYSTEMS

- Many countries provide opposition mechanisms in their patent systems. Opposition systems offer third parties the an opportunity to oppose the grant of a patent within a certain period of time provided by the applicable law. An opponent must allege at least one of the grounds for opposition among those that are prescribed in the applicable law. Opposition procedures are closely related to the patent granting procedure. An opposition may be requested soon before the grant of a patent (pre-grant opposition) or after the grant of a patent (post-grant opposition). In some countries, an opposition may be filed within a certain time period immediately after the publication of the application for a patent and before the examination phase, in which case the procedure resembles, to a certain extent, the so-called third party observation system. It is possible to combine pre-grant and post-grant opposition systems. India, for example, provides both a pre-grant and a post-grant opposition system. One of the main objectives of the opposition system is to provide a simple, quick and inexpensive mechanism that ensures the quality and validity of granted patents by allowing an early rectification of invalid patents. In general, opposition proceedings are interpartes procedures conducted before the patent office, not a court. In some patent offices, they are held before a special opposition board.
- 16. Pre-grant opposition often starts once the examination of a patent application has been completed by a positive result. The Office publishes its intention to grant the patent on the claimed invention contained in the application, and provides a certain time period during which an opposition can be filed. The opponent shall state the grounds for opposition and submit any evidence. If no opposition is filed during that period, the patent will be granted. If an opposition is filed, the applicant will be notified of that fact, together with the grounds for opposition and the evidence (for example, prior art documents that demonstrate lack of inventive step). The applicant will be given the opportunity to comply with the requirements under the applicable law, and to make observations, within the prescribed time limit. In accordance with the applicable law, the opponent has the possibility to respond to the observations made by the applicant. Based on the submissions by the opponent and the applicant, an examiner or any other person entrusted to decide on opposition cases under the applicable law will make a decision as to whether the patent shall be granted or not.
- 17. In some countries, the pre-grant opposition system is designed in such a way that it starts after the publication of the patent application and before substantive examination. Once the patent application is published, an opposition may be filed within a certain time period prescribed under the applicable law. The opponent shall state the grounds for opposition and submit any evidence. If no opposition is filed during that period, the substantive examination will be carried out. If an opposition is filed, the applicant will be notified, and given an opportunity to make observations and/or amend the application within the prescribed time period. The conclusion of the opposition will be notified to both the applicant and the opponent.
- 18. Post-grant opposition starts once the patent is granted. Once the fact that a patent has been granted is published, an opposition may be filed with evidence within a certain time period prescribed in the applicable law. Similar to the pre-grant opposition, the patentee will be notified about that fact, and be given the opportunity to comply with the requirements under the applicable law, and to make observations, within the prescribed time limit. In accordance with

the applicable law, the opponent has the possibility to respond to the observations made by the patentee. Based on the submissions by the opponent and the applicant, whoever is entrusted to decide on opposition cases under the applicable law will make a decision as to whether the patent shall be maintained, <u>amended</u> or revoked.

- 19. Since one of the objectives of the opposition system is to provide a simple mechanism to ensure the quality and validity of granted patents, <u>procedural and substantive requirements</u> <u>provided by the applicable laws regarding opposition systems have certain common aspects.</u> However, there are differences in the details. Some of these differences are the following:
 - (i) the timeframe during which an opposition may be filed: the opposition period may start immediately after the publication of the patent application, after the completion of the substantive examination with a positive result and/or after the grant of the patent;
 - (ii) entitlement to file an opposition: in many national laws, any party, including the applicant or the patentee, may file an opposition. However, some laws provide that any third party (excluding the applicant or the patentee) may file an opposition;
 - (iii) the length of the opposition period: the length of the opposition period varies from country to country. Among the countries listed in Chapter V, the duration varies from two to six months for pre-grant opposition and from six to 12 months for post-grant opposition;
 - (iv) the grounds for an opposition: in many countries, the requirements regarding novelty, inventive step, industrial applicability, sufficiency of disclosure and addition of new matter going beyond the original disclosure are grounds for an opposition.

 Non-compliance with the requirements concerning the exclusions from patentable subject matter also forms part of the grounds for an opposition in many countries. Some countries accept an opposition on the grounds that an applicant/patentee is not entitled to the right to a patent, or on other grounds covering all requirements that should be fulfilled to obtain a patent. They include, for example, the fact that information regarding corresponding foreign applications was not submitted, the source or geographical origin of biological material used in the invention was not disclosed, or the essential formalities were not complied with.
 - (v) reviewing officers: the opposition may be conducted by an examination division or the proceedings may be held before a special opposition board;
 - (vi) inter partes procedural requirements: formal and procedural requirements relating to, for example, a request, notification to parties, arguments, evidence, oral hearing and final decision depends on the applicable law, most likely based on the general civil procedural law of each country:
 - (vii) opposition fee: In many countries, the payment of an opposition fee is required to file an opposition.
- 20. An appeal against the final decision of the opposition body is generally possible, often to a court. It should be noted that, according to Article 62.5 of the TRIPS Agreement, <u>final</u> administrative decisions <u>in procedures concerning the acquisition and maintenance of intellectual property rights as well as the administrative revocation and <u>inter partes procedures</u> shall be subject to review by a judicial or quasi-judicial authority.</u>

21. _The number of patent applications/patents with in respect to of which oppositions are filed is not very high. For example, The opposition rates at the European Patent Office (EPO), the German Patent Office and the Korean Intellectual Property Office are 6.0%, 4.6% and 1.3%, respectively, in 2007 in 2008, 2009 and 2010 was 5.32%, 4.7% and 5.2% respectively. Information on other countries' statistical data on oppositions is available in the Annex to this document.

III. RATIONALE AND OBJECTIVES

- 22. The patent system intends to promote innovation, dissemination and transfer of technology by granting a limited exclusive right to prevent others from using a patented invention without the consent of the patent owner and, at the same time, requiring the patent owner to fully disclose the invention to the public. In order to meet this objective, the patent law lays down strict requirements, both procedural and substantive, to obtain patent protection. Those requirements are fundamental to a functioning patent system, as they were created in order to ensure that only those inventions that are "worth" protecting for the purposes of facilitating innovation and meeting the broad public interest would obtain patent protection.
- However, in reality, it may nevertheless happen that an invention that does not fully meet the requirements under the applicable law obtains a patent. For example, a substantive examiner may overlook a piece of prior art and inadvertently reach a positive decision regarding the patentability of the claimed invention. Such a situation should not be necessarily considered as low quality examination in a given country, since the piece of prior art could be published in an exotic language or in an isolated publication. Further, in some countries, only formality examination is conducted. In order to rectify the grant of a deficient patent, in general, a patent revocation procedure is provided either before a competent court or before an administrative/quasi-judicial body the decision of which can be reviewed by a judicial body. The opposition system provides an additional administrative layer of review that prevents the grant of invalid patents through the participation of third parties to the review process. The idea is that the participation of third parties, who may be well informed about the technology concerned,⁴ would complement the resources available to the patent office, and would increase the credibility of granted patents. Since the opposition procedure is provided just before or after the grant of the patent, it allows an early rectification of invalid patents. The possibility to rectify invalid patents at an early stage may be is also beneficial for a patentee, since the patentee can have more trust in the validity of his patent. Thus, a patent granted on an invention that has gone through opposition proceedings would be considered as having a higher credibility in terms of its compliance with novelty, inventive step and other requirements of patent law.
- 24. Compared with a to the review process before a court, the opposition system has various advantages. They include:
 - (i) the opposition procedure, which is an administrative process, is generally simpler, quicker⁵ and less expensive;

However, according to the statistics received from some Member States, there was a case where the share of the applications/patents on which oppositions were lodged was high (see the information received from Pakistan in the Annex to this document).

The third parties could be, *inter alia*, competitors of the applicant or patentee having a good knowledge of the technological area concerned and who have their business interest in eliminating deficient patents.

In a study related to the EPO, it was reported that the duration of the opposition procedure, from filing the notice of opposition till the delivery of the decision by the Opposition Division, was about

- (ii) an opposition may be filed by any person (or any third party), while a patent revocation procedure may, in some countries, be initiated only by a party who fulfills certain conditions, for example, being an interested party or being adversely affected by the decision subject to the appeal. Therefore, the opposition system takes into account the wider knowledge of the general public;
- (iii) the decision of an opposition board is made by examiners and other officers with technical expertise, while a judge may not always be familiar with the technology concerned.
- 25. While the primary purpose of opposition systems is to ensure that patents are not granted to creations which do not meet the patentability requirements, they also target another important objective, which is to safeguard the scope of information in the public domain. Although revocation proceedings are available, the grant of patents of unsatisfactory quality may have a limiting effect on the public domain. In other words, once a patent is erroneously granted, the claimed invention, which otherwise would remain in the public domain, can be used by others only with the authorization of the patentee.
- Viewed from the angle of innovation policy, the positive effect of the patent system on innovation can only be achieved by valid patents complying with all the requirements of the applicable law. Patent opposition procedures, along with other revocation procedures available under the national law, can be considered as one of the possible tools available in the patent system which support the grant of valid patents. It is in keeping with the broad policy objectives of the patent system and in the interest of various stakeholders, such as government, industry, academia, the patentees and third parties, that patents are granted only to genuine inventions that meet all the requirements under the applicable law. While the grounds for opposition may differ from country to country, the most common grounds provided under national laws, such as the lack of novelty, inventive step or industrial applicability and non-compliance with the requirement of sufficient disclosure, are grounds that are often invoked by patent examiners to reject patent applications. By ensuring a high credibility and validity of granted patents, the opposition mechanisms, along with other revocation procedures, mitigate the problem of cost that patents of unsatisfactory quality may create. Patents that meet all the requirements imposed by patent laws may be reliably enforced in court and licensed to others. At the same time, such patents also provide the greatest value to the public and clarify the extent to which others may approach the protected invention without infringing it.
- 27. On the other hand, the opposition system also incurs costs, and is not always free from criticism. First, in order to set up an opposition procedure, the administration (the patent office) needs to have relevant resources, such as technically qualified examiners who are capable of reviewing the initial decision or other officers who will conduct the opposition proceedings. This

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1.9 year on average (See D. Harhoff, K. Hoisl, B. Reichl, and B. Van Pottelsberghe, Patent Validation at the Country Level – The Role of Fees and Translation Costs, Research Policy, Elsevier, 2009, v. 38(9)). However, it was reported that in some technical fields the median duration of the opposition and appeal at the EPO can be estimated in average at about 3.07 years. (See S.J.Graham et,al. Patent Control: A Comparison of U.S. Patent Reexamination and the European Patent Oppositions, August 2002).

Recommendations 16 and 20 of the WIPO Development Agenda touch upon the public domain issues.

In addition to high social cost, invalid patents create cost for patentees of such patents if the patentees need to spend resources in fighting off litigation involving patents with questionable validity.

As an alternative, a patent Office which does not have resources to conduct substantive review may conclude cooperation agreement with other offices. For example, while the Intellectual Property Office of Singapore does not provide the opposition procedure, upon cooperation

could be relevant particularly for offices in developing countries which may have more difficulty in hiring technically qualified staff and have perhaps a more limited access to technological material on prior art to carry out substantive examination.9 In this context, it is recalled that the opposition procedures are closely related to the patent granting procedures. Since high quality substantive examination requires human and financial resources, it seems that opposition systems are utilized in the national/regional patent granting procedures either as a supplementary mechanism to the substantive examination by examiners or as a complementary mechanism to substantive examination. Taking the former approach, patent examiners are primarily tasked to conduct substantive examination, and only where they made affirmative decisions, the general public has the opportunity to supplement the examination shortly before or after the patent grant. On the other hand, according to the second approach, the general public plays a complementary role in examining patent applications, thus "examining" published patent applications which have not been reviewed by patent examiners yet. In the latter case, one researcher stated that such procedures allow the opposition to a patent at a wrong time, as the only information available for third parties at that early stage would be the patent specification as filed. 10 Nevertheless, different approaches are possible depending on the resources available in the patent office examination sector and in the general public, as well as on the allocation of tasks among different "agents" in order to provide an optimal examination/review mechanism. Therefore, it is considered important that the patent law of each country explore various mechanisms which would allow detecting and challenging the grant of invalid patents at an early stage of the patent granting procedure, taking into account the available resources.

- 28. The opposition is subject to the payment of fee in most countries. However, in general, such fee is not significant compared to patent litigation costs. 11 Opposition fees are set by the national patent offices reflecting, in general, the marginal costs for the patent offices to review the applications or patents under opposition, and countries are free to make such procedures free of charge or to provide various flexibilities to various opponents, for example to natural persons or small and medium sized enterprises, if they wish to do so. While, at the national level, various fee-related policies can be adopted by the patent offices, it is most likely that opponents should bear the cost of hiring professional advisors to assist them in preparing and filing the opposition case. The fee related to hiring professional advisors is particularly relevant when the opponent is a national or resident of another country and, therefore, according to the national law, may be obliged to hire a local advisor to file an opposition. 12
- 29. One of the The major challenges in designing an opposition procedure, however, is that it could substantially delay the whole process of finalizing the grant of a patent. Where a number of oppositions based on different items of prior art and on different grounds are filed, the

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agreements concluded with other patent offices, such as the Austrian Patent Office, IP Australia, the Danish Patent and the Trademark Office and the Hungarian Patent Office, it outsources search and examination work in relation to patent applications, as well as the re-examination of the granted patent(s) initiated by the Registrar or any person to revoke a patent.

There are various projects undertaken by WIPO to improve access of developing countries to prior art databases. These initiatives are described in documents SCP/13/5 and SCP/14/3.

Jakkrit Kuanpoth, Appropriate Patent Rules in the Developing Country – Some Deliberations Based on Thai Legislation, Journal of Intellectual Property Rights, Vol. 13, Sept 2001, 447-455.

- For example, it was estimated that the patent litigation cost in Germany could be around EUR 50.000 (cost of 1st instance) and EUR 90.000 (cost of second instance) (See Communication from the Commission to the European Parliament and the Council, Enhancing the Patent System in Europe, Brussels, 3.4.2007, COM(2007)). The fee for filing an opposition in Germany with DPMA is EUR 200.
- Article 2(3) of the Paris Convention (and Article 3(2) of the TRIPS Agreement by reference to the Paris Convention), allows certain discrimination against nationals of other countries including in relation to the requirement that foreigners should appoint a local agent.

applicant (or the patentee) shall argue against each opponent, and shall defend his invention. Since anyone can file an opposition, a great number of oppositions could be filed in complex cases. ¹³ On the one hand, a A pre-grant opposition system supports legal certainty by allowing a pre-review of the patentability of an invention by third parties before granting the patent. In other words, it increases the validity of granted patents. On the other hand However, the pre-grant opposition period holds all other applications pending before the office, which will never be opposed introduces an additional period during which all the applications are pending before the patent office prior to the grant of the patents. In practice, only a small number of applications are opposed. 14 Consequently, although it is a matter of several months, in general, there is an inevitable delay across the board in granting patents, including for applications which were not subject to opposition, for the period during which an opposition could be filed. In a post-grant opposition system, the delay will only be applicable, in principle, to those affected by oppositions and this does not have an impact on those patents not subject to any opposition. However, Wwhile the post-grant opposition system does not extend the period between the filing of the application and the grant of the patent, during the opposition period, the enforceability of the opposed granted patent is could be uncertain. Another effect of the post-grant opposition could be that such patents may not be considered of a high commercial value, since potential licensees may hesitate to enter into licensing agreement due to the uncertainty over the validity of the patent during the opposition period. 16 In short, policy makers need to consider two elements: on the one hand, an additional review process may have a positive effect on the promotion of innovation by increasing the quality and the validity of granted patents. On the other hand, such an additional process may have a negative effect on the promotion of innovation by delaying the granting process, and introduce a period of uncertainty as regards the enforceability of opposed patents and hold up licensing deals.

30. The publication of relevant information is a prerequisite for pre-grant and post-grant opposition. However, the scope of published information, for the purposes of opposition, may vary from one country to another, ¹⁷ from the publication of all information contained in patent applications, including the detailed description of inventions, in some countries, to only the bibliographic data ¹⁸ in other countries. However, it is to be noted that even in those countries where only the bibliographic data is published, the patent offices make available to the public the full contents of patent applications or patents for inspection, and allowing third parties to

For example, the Oncomouse case (EP 0169672) received 17 oppositions, and Edinburgh/stem cells case (EP 0695351) received 14 oppositions. A study shows that the likelihood of opposition increases with patent value, and that opposition is particularly frequent in areas with strong patenting activities and with high technical or market uncertainty. (Dietman Harhoff, Markus Reitzig "Determinant of opposition against EPO patent grants - the case of biotechnology and pharmaceuticals", International Journal of Industrial Organization, 22 (2004), 443-480).

The statistical data submitted by the Member States appears to support this conclusion. See Annex to this document.

This particularly could be the case for inventions in some technological areas which have higher probability of being opposed than patents in other areas. In addition, the possibility of the patents to be objected by third parties, if such mechanism exists under the applicable law, would probably also be taken into account by the potential licensees in the decision making process.

According to Article 12 of the Paris Convention, while each country of the Union has to establish a special industrial property service for the communication to the public of, *inter alia*, patents through its publication, the publication is only mandatory in relation to essential data such as, the names of the proprietors of patents granted, with a brief designation of the inventions patented. Thus, the Paris Convention does not specify how patents should be "communicated to the public".

Such as the name and address of the applicant, inventor and patent agent; the title of the invention; the date of the filing of the application; and the date, place and serial number of the earlier application the priority of which is claimed.

In addition, some patent laws allow the alleged infringer to intervene in the opposition proceeding in response to the request of the patentee, whose patent is being opposed, to cease alleged infringement.

access the entire applications or patents in the pre-grant or post-grant opposition context. In addition, easier access to prior art information by third parties will make it more easy for them to substantiate their opposition claim.

- 31. Even if a third party, often a competitor, has access to relevant information and has evidence that could be sufficient to file an opposition to prevent a patent to be granted or to revoke a granted patent, he may not necessarily launch the opposition in view of his overall business interest. For example, a patent may be so trivial that it can easily be designed around. An opposition system is only one of the various mechanisms that support the patent administration in fulfilling the public policy objectives, and an effective opposition system can be designed only in connection with the patent-granting procedures and other revocation mechanisms in a given country.
- The changes made in the Japanese opposition system during the past 15 years are interesting from the above policy perspective. Prior to 1996, the Japan Patent Law provided a pre-grant opposition system which allowed the public to complement the examination by substantive examiners. However, concerns over the delay in granting a patent became stronger, and in 1996, the pre-grant opposition system was replaced by a post-grant opposition system. Consequently, two mechanisms to challenge the validity of granted patents coexist in Japan, i.e., a post-grant opposition system and an administrative appeal for revocation of a patent. The post-grant opposition can be filed by anyone within six months from publication of the gazette containing the patent. However, the opponent cannot fully participate in the review process, which is conducted between the patent office and the patentee. The system was designed so that the patent office reviews its prior decision based on the evidence provided by the opponent and the counter-argument, if any, submitted by the patentee. 21 On the other hand, the appeal for revocation of a patent, which is an *inter partes* procedure, can be filed by an interested party any time after the registration. Such a dual system was later found problematic, since the same patent could be subject to both post-grant opposition and appeal for revocation in two separate cases. The situation became even more complicated after the Supreme Court's decision in April 2000, in which the Court held that judicial courts were capable of reviewing the validity of patents regardless of the status and outcome of the administrative appeal proceedings at the Japan Patent Office.²²
- 33. In order to streamline the post-grant review procedures, the post-grant opposition system was abolished in 2004, and the mechanism to challenge a granted patent was streamlined into a single procedure, namely the administrative appeal for revocation of a patent. The revised appeal for revocation of a patent allows, in principle, anyone to file an appeal. In order to maintain a simpler and cheaper option to assist invalidating patents that have been inadvertently granted, the Office has created a mechanism that allows third parties to submit,

Within the Program on Modernization of IP Institutions, WIPO have assisted national IP Offices in making their databases available to public through digitations of paper documentation.

Fujitsu v. Texas Instruments, 1998(O)No. 364, Supreme Court, April 11, 2000.

In connection with the Structural Impediments Initiative (SII) negotiated between the United States of America and Japan in late 1980s, the former argued that a great number of pre-grant oppositions filed by Japanese firms on the patent applications filed by US firms purposely delayed the grant of patents on US inventions, and thus unfairly benefitted the Japanese industry. Japan responded that its opposition system had not delayed the patent granting process, since among a small number of opposition cases, it was only in very exceptional cases where a great number of opposition requests had been filed on one application.

Goto A, Motohashi K. Construction of a Japanese Patent Database and a First Look at Japanese Patenting Activities. Research Policy 2007; 36:1431-42. The authors concludes that the change to the post-grant opposition system from the pre-grant opposition system resulted in the Japan Patent Office accelerated the granting of patents, and all pending patents under the old pre-grant opposition period prior to 1996 were processed in that year.

free of charge, any information which may be relevant to various patentability requirements even after the grant of a patent.²³

- 34. The experience of China with designing an opposition procedure is also worth considering. China had a pre-grant opposition procedure prior to 1992, which was changed to a post-grant opposition system due to delays associated with the grant of a patent. Prior to 2000, both systems existed: a post-grant opposition procedure as well as a post-grant invalidation procedure. The two systems differed in the grounds for invalidation and time period allowed for bringing an action. Particularly, the invalidation procedure could not be initiated until an opposition procedure involving the same patent was concluded. In 2000, the patent law was amended to abolish the post-grant opposition system. The amendment was required by the fact that the patentee could be subject to multiple attacks and because it over-burdened the State Intellectual Property Office (SIPO). At present, the patent invalidation procedure is the only mechanism available for challenging the validity of a patent.²⁴
- 35. Although it may be still be too early to draw any conclusions from the changes that took place in Japan and China which were made in the specific contexts of these countries, it appears that designing a national opposition system is linked to the availability of other possibilities of reviewing the validity of patents. It seems that if more than one review mechanism exists in the national patent system, an additional mechanism should have additional benefits and should not just be a duplication of another review process. This could complicate the procedures, delay the whole process of delivering the final administrative decision and increase legal uncertainty.
- 36. While national/regional opposition systems are different, in view of the above paragraphs, non-exhaustive factors that may contribute to an enabling environment for an effective opposition system may include:
 - (i) easy access to patent applications and patents that are laid open for opposition;
 - (ii) easy access to prior art information;
 - (iii) availability of human resources capable to conduct opposition procedures;
 - <u>(iv)</u> reasonable opposition timeframe which balances the interests of applicants/patentees and third parties;
 - (v) reasonable formalities and procedures that allow effective conduct of opposition procedures: and
 - (vi) appropriate fee mechanisms.

States, Research Policy, 31 (2002)).

While, at present, the academic research providing conclusive evidence on the role of the oppositions systems in enhancing innovation in Japan is scarce, one paper focusing on the topic of patents and incentive to innovate in Japan and the United States of America suggests that the Japanese first-to-file system as compared to the (soon-to-be-replaced) first-to-invent in the United States of America places more information in the public domain sooner, induces the filing of a patent application sooner in the innovation process; and that the opportunity for pre-grant opposition strengthens the incentives to monitor competitors' patent filings early on. (See Wesley Cohen et al., R&D and Spillover, Patents and the Incentives to Innovate in Japan and the United

Haitao Sun, Post-Grant Patent Invalidation in China and in the United States, Europe, Japan: A Comparative Study, 15 Fordham Intellectual Property, Media & Entertainment Law Journal, 2004.

IV. INTERNATIONAL LEGAL FRAMEWORK

37. No international treaty regulates opposition systems as such. Countries are free to provide, or not to provide, an opposition mechanism in their national laws. While substantive requirements with respect to opposition proceedings are not dealt with in existing treaties, some general procedural requirements prescribed in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Patent Law Treaty (PLT) may also be applicable to opposition procedures.

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS AGREEMENT)

- 38. Article 62.4 of the TRIPS Agreement provides that, where a Member's law provides administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, they shall be governed by the general principles set out in Article 41.2 and 3. Article 41.2 and 3 reads:
 - "2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.
 - "3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard."
- 39. Further, Article 62.5 states that final administrative decisions in the above procedures referred to under Article 62.4, including administrative revocation and *inter partes* opposition procedures, shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.
- 40. In addition, as a general rule, according to Article 62.2, Members shall ensure that the procedures for grant, subject to compliance with the substantive conditions for acquisition of the right, permit the granting of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

PATENT LAW TREATY (PLT)

- 41. According to PLT Article 10(1), non-compliance with certain formal requirements with respect to an application may not be a ground for revocation or invalidation of a patent, either totally or in part, except where the non-compliance with the formal requirement occurred as a result of a fraudulent intention. Those formal requirements are: (i) form or contents of application (PLT Article 6(1)); (ii) formal requirements relating to request form, fees and priority document (PLT Article 6(2), (4) and (5)); (iii) form and means of transmittal of communications (PLT Article 8(1) and (3)); and (iv) language and signature of communications (PLT Article 8(2) and (4)). In other words, once a patent is granted, it shall not be revoked or invalidated on the grounds of non-compliance with the above formal requirements.
- 42. In addition, PLT Article 10(2) provides that a patent may not be revoked or invalidated, either totally or in part, without the owner being given the opportunity to make observations on the intended revocation or invalidation, and to make amendments and corrections where permitted under the applicable law, within a reasonable time limit.

- 43. Further, PLT Article 11 provides the extension of a time limit for an applicant's action before the patent office under certain conditions, and PLT Article 12 requires Contracting Parties to provide reinstatement of rights where an applicant lost his rights because of the failure to observe a time limit, if the failure occurred in spite of due care required by the circumstances or was unintentional. However, in accordance with PLT Rules 12(5)(vi) and 13(iv), no Contracting parties shall be required to grant a relief under PLT Article 11 or reinstatement of rights under Article 12 in respect of a time limit for an action in *inter partes* proceedings. In other words, a Contracting party is free to provide, or not to provide, the extension of a time limit and/or the reinstatement of rights regarding a time limit for an action in *inter partes* opposition proceedings.
- 44. However, when adopting these Rules, the Diplomatic Conference adopted Agreed Statement No. 5, stating that while it was appropriate to exclude actions in relation to *inter partes* proceedings from the relief provided by Articles 11 and 12, it was desirable that the applicable laws of the Contracting Parties provide appropriate relief in those circumstances which takes into account the competing interests of third parties, as well as the interests of others who are not parties to the proceedings.

V. EXAMPLES OF OPPOSITION PROCEDURES

45. As mentioned earlier, each country may have its own reasons to introduce opposition procedures, or not to introduce such procedures, under its national law. Among the countries that have an opposition system, procedural and substantive requirements have some common aspects, but are different in details, reflecting the various needs. Such differences may include: (i) pre-grant or post-grant opposition; (ii) entitlement to file an opposition; (iii) period for filing an opposition; (iv) grounds for an opposition; (v) *inter partes* procedural requirements, such as a request, notification to parties, arguments, evidence, oral hearing, final decision etc.; and (vi) an appeal against the final decision (competent authority, time limit to file an appeal etc.). The following paragraphs illustrate existing opposition systems in a number of countries/regions.

AUSTRALIA

- 46. Australia operates a pre-grant opposition system for standard patent applications, where any person may oppose the granting of a patent within three months of acceptance of the application being advertised in the Official Journal of Patents.
- 47. According to Section 59 of the Patents Act, the Minister or any other person may, in accordance with the Regulations, oppose the grant of a standard patent on one or more of the following grounds, but on no other ground:

There are two types of patents in Australia, the "standard" patent and the "innovation" patent (similar to utility model). Oppositions to innovation patents can only be initiated after the patent has been granted and then certified. For further information on innovation patents, see the submission of Australia available on the SCP electronic forum website at:

http://www.wipo.int/export/sites/www/scp/en/meetings/session_17/opposition/australia.pdf.

Section 49 (1) of the Patents Act provides that, subject to Section 50, the Commissioner must accept a patent request and complete specification relating to an application for a standard patent, if: (a) the Commissioner is satisfied that the invention satisfies the criteria mentioned in paragraph 18(1)(b), i.e., novelty and inventive step; and (b) the Commissioner considers that:

(i) there is no lawful ground of objection (other than a ground in respect of paragraph 18(1)(b)) to the request and specification; or (ii) any such ground of objection has been removed.

- (i) that the nominated person is either (a) not entitled to the grant of a patent for the invention; or (b) entitled to the grant of a patent for the invention, but only in conjunction with some other person;
- (ii) that the invention is not a patentable invention;
- (iii) that the specification filed in respect of the complete application does not comply with subsection 40(2) or (3).²⁷
- 48. As provided in Section 60 of the Patents Act, the opposition is heard by the Commissioner which must decide the case in accordance with the Regulations. The Commissioner must give the applicant and the opponent a reasonable opportunity to be heard before deciding the case. The Commissioner may, in deciding the case, take into account any ground on which the grant of a standard patent may be opposed, whether relied upon by the opponent or not. The applicant, and any opponent, may appeal to the Federal Court against a decision of the Commissioner under this Section. Oppositions can also arise with regard to procedural matters including:
 - (i) amendments: under Section 104(4) of the Patents Act, any person may oppose the allowance of an amendment. Section 102 of the Patents Act provides that amendment of complete specification are not allowable if amended specification would claim matter not in substance disclosed in the filed specification;
 - (ii) extensions of time: under Section 223(6) of the Patents Act, any person may oppose the granting of an extension of time;
 - (iii) extension of term for a pharmaceutical patent; under Section 70 of the Patents Act, any person may oppose the grant of an extension of term under Section 75 but only on the grounds that Section 70 (defines what subject matter is available for extension of term) or Section 71 (relating to the form and timing of an application) is not met;
 - (iv) amendment of the Register or a patent: under Regulation 10.7(4) of the Patents Regulations 1991, any person may oppose the making of an amendment of the Register;
 - (v) grant of a licence to exploit an invention: under Regulation 22.21(4) of the Patents Regulations 1991, a person who receives a copy of an application for a licence can oppose the granting of that licence.
- 49. According to the data submitted by the Australian Patent Office, there were 130 oppositions over 27,594 applications filed²⁸ in 2006/2007 reporting period, compared to 109 over 27,979 applications filed in 2007/2008, 167 over 26,259 applications filed in 2008/2009, 120 over 25,443 applications filed in 2009/2010 and 143 over 26,473 applications filed in 2010/2011.

The applications filed number does not include provisional filings, but does include both innovation and standard patent applications.

Subsection 40(2) of the Patents Act provides that a complete specification must (i) describe the invention fully, including the best methods known to the applicant of performing the invention, and (ii) end with a claim or claims defining the invention. Article 40(3) states that the claims or claim must be clear and succinct and fairly based on the matter described in the specification.

BRAZIL

- 50. The Industrial Property Law of Brazil²⁹ provides administrative nullity procedures which can be instituted either *ex officio* or at the request of any person having a legitimate interest, within a period of six months from the date of the grant of the patent.³⁰
- 51. The administrative nullity proceedings can be instituted on any of the following grounds:³¹
 - (i) the legal requirements on patentability were not satisfied;
 - (ii) the specifications and claims did not comply with requirements of sufficient disclosure and enablement;
 - (iii) the object of the patent extends beyond the contents of the application filed originally;
 - (iv) any of the essential formalities that are indispensable to granting has been omitted during the processing thereof.
- 52. After acceptance of the nullity request, the patent holder is notified to that effect and requested to submit comments in relation to the request within a period of 60 days from the date of receipt of such notification. After the expiration of those 60 days, whether or not comments were submitted, the National Institute of Industrial Property (INPI) will issue an opinion and request the patent holder and the person who filed the nullity request to submit their comments within an additional period of 60 days.³²
- 53. After the time limit of 60 days has elapsed, even if no comments have been submitted, the case is decided by the President of INPI upon the results of technical and legal reports submitted to the President by the relevant departments of INPI which have examined the case. The decision of the President is final at the administrative level³³ and could be appealed in court. Nullity of a patent shall produce effects from the filing date of the application.³⁴

DENMARK

- 54. The Consolidated Patents Act³⁵ provides a post-grant opposition. Granted Danish patents may be opposed by any person within nine month of the date of the publication of the grant of a Danish patent in the Danish Patent Bulletin.³⁶
- 55. The notice of opposition must be filed in writing and contain, *inter alia*, a statement of the extent to which the Danish patent is opposed and of the grounds on which the opposition is based, as well as the facts and evidence in support of the grounds.
- 56. As provided by Section 21 of the Consolidated Patents Act, the opposition can only be based on the following grounds: the subject matter does not fulfill the patentability criteria (industrial applicability, novelty, inventive step), the invention is not sufficiently disclosed to allow

The Industrial Property Law No.9.279 of May 14, 1996.

Article 51 of the Industrial Property Law.

Article 50 of the Industrial Property Law.

Article 53 of the Industrial Property Law.

Article 54 of the Industrial Property Law.

Article 48 of the Industrial Property Law.

The Consolidated Patents Act No. 91 of 28 January 2009.

Section 21 of the Patents Act.

a person skilled in the art to carry it out; and the content of the patent extends beyond the content of the application as filed.

- 57. After a hearing phase with the parties of the opposition case, the Opposition Division renders a decision. The result can be to reject the opposition, to revoke the patent or maintain the patent in amended form.
- 58. A notice of appeal must be filed to the Danish Board of Appeal within two months of notification of the opposition decision, and the fee for appeal must be paid.

EGYPT

- 59. A pre-grant opposition procedure before the Egyptian Patent Office is provided in Egypt. Article 16 of the Law on the Protection of Intellectual Property Rights³⁷ provides that any party may submit to the Patent Office a written notice opposing the grant of a patent and stating the reasons thereof within 60 days from the publication of the application acceptance in the Patent Gazette. Such an opposition is the subject to the payment of a fee which will be reimbursed in case the opposition is accepted.
- 60. In cases where the application relates to defense, military production, security or has health significance, the relevant Ministry may oppose the grant of the patent within 90 days from the date of publication of the application.³⁸
- 61. After the acceptance of the opposition request, the Office will notify the applicant by transmitting a copy of the opposition request within 7 days from the date of its receipt by the Office. The applicant may respond to the arguments contained in the opposition request within 15 days from the day he was notified about it. The Office then transmits to the opposing party a copy of the response of the applicant within 7 days from the date of its receipt by the Office.³⁹
- 62. The opposition is examined by a Committee which is composed of a chairman who is a judge from the appeal courts, or a person of the same rank from the members of the judicial system, an associate judge from the State Council (administrative tribunal) as well as three other members who have relevant expertise. The Law does not provide for the mandatory representation of the Patent Office in the work of the Committee. In certain cases, the Committee may decide to seek an advice of an expert who can be an official of the government or any other external expert.⁴⁰ The Committee delivers the decision within 60 days from the date of the filing of the opposition notice.⁴¹ The Office will then notify the parties about the decision taken on the opposition, stating the reasons of the decision within 10 days from the date of its issuance.⁴²
- 63. The decision of the Committee may be appealed either by the Patent Office or any interested party to the Administrative Tribunal within 60 days from the date of notification of the decision.

Law on the Protection of Intellectual Property Right 82 of 2002.

Article 17 of the Law on the Protection of Intellectual Property Right 82 of 2002.

Rule 24 of the Regulations of Law 82 of 2002.

Rule 27 and 28 of the Regulations of Law 82 of 2002.

Article 36 of the Law on the Protection of Intellectual Property Right 82 of 2002.

Rule 29 of the Regulations of Law 82 of 2002.

FINLAND

- 64. According to the Patents Act of Finland, 43 any person, including the proprietor of the patent, can file an opposition against a granted patent. The opposition must be filed in writing within nine months from the date of the grant of the patent and it must specify the grounds on which it is made. The proprietor of the patent will be notified thereof and he will be given an opportunity to make observations on the opposition. According to Section 25 of the Patents Act, a patent shall be revoked on the following grounds:
 - (i) the invention lacks novelty, inventive step or industrial applicability;
 - (ii) the patent relates to an invention the description of which is not sufficiently clear to enable a person skilled in the art to carry out the invention;
 - (iii) the patent contains subject matter not included in the application as filed.
- 65. At the moment, there is no opposition fee. However, an opposition fee must be paid when the opposition is filed against a patent which will be granted on or after November 1, 2011.
- 66. According to the National Board of Patents and Registration of Finland, the number of oppositions filed was 21 in 2008, 26 in 2009 and 23 in 2010.⁴⁴

GERMANY

- 67. Under the Patents Act of Germany, a notice of opposition against a granted patent can be filed at the German Patent and Trade Mark Office (DPMA). The opposition must be filed at the DPMA within three months from the publication of the patent grant. The time limit is observed only if all admissibility requirements are met within the specified period. In particular, the notice of opposition must be sufficiently substantiated. Reestablishment of rights is not available if the time limit for filing an opposition has not been observed. Under the Patent Costs Act⁴⁶ the filing of an opposition is subject to a fee of 200 EUR, to be paid to the DPMA within the opposition period.
- 68. Anyone can oppose a patent, except the patent owner himself.⁴⁷ In case of usurpation, only the injured party can file an opposition against the patent.
- 69. The notice of opposition must be filed with the DPMA in writing, bear a hand-written signature, and comply with all other requirements for admissibility. These include, for example, the requirement that the notice of opposition must not leave any doubt as to the opponent's identity. In the reasoning, the opponent must specify the facts supposed to lead to the conclusion that the patent has to be revoked in full or in part. The relevant actual facts must be explained in detail in such a way that the DPMA and the patent owner need not further investigate the matter in order to examine whether or not there is a ground for revocation.

⁴³ Patents Act 15.12.1967/550.

Further statistical data on opposition in Finland is available in the Annex to this document.

Section 59(1) of the Patents Act [Patentgesetz].

⁴⁶ [Patentkostengesetz].

The patent owner, however, can abandon his patent or request a limitation of his patent before the DPMA.

Section 21(3) of the Patents Act [Patentgesetz] states that: "3. the essential contents of the patent have been taken from the descriptions, drawings, models, appliances or equipment of another, or from a process used by another, without the consent of said person (usurpation);".

- 70. Section 21(1) of the Patents Act sets out the grounds for revocation on which an opposition can be based. According to this provision, a patent will be revoked if:
 - (i) the subject matter of the patent is not patentable under Sections 1 to 5 of Patents Act;
 - (ii) the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;
 - (iii) the essential elements of the patent have been taken from the descriptions, drawings, models, appliances or equipment of another person, or from a process used by another person, without his consent, and
 - (iv) the subject matter of the patent extends beyond the content of the application as originally filed with the competent authorities.
- 71. The opposition proceedings are conducted by the Patent Division of the DPMA, which decides whether a patent shall be revoked or maintained. As a rule, the decision is taken by a panel of three technical members of the Patent Division. If the case involves special legal difficulties, a legal member of the Patent Division joins the panel.
- 72. According to the DPMA, 665 oppositions were filed in 2010. Opposition proceedings conducted in 2010 were as follows: 75 cases by the abandonment of the patent by the patent owner, 87 cases by non-payment of the annual fee, 278 cases by revocation of the patent by the DPMA and 538 cases by a decision of the DPMA to maintain the patent in full or in part. In 61 cases, the patent owner lodged an appeal against the revocation of the patent. In 123 cases, an appeal was lodged against the decision of the DPMA to maintain the patent in full or in part.

HONDURAS

- 73. According to Article 55 of the Industrial Property Law of Honduras, once the application is in order, or any deficiency of form has been corrected, an individual substantive examination of the application is conducted in which it is verified whether the general conditions of novelty, inventive step and industrial applicability are satisfied, and the publication of a relevant notice (notice of publication) is ordered in the Official Journal, *La Gaceta*, on three consecutive occasions, each 30 days apart. This publication will provide details of the applicant's name and a summary of the invention.
- 74. Any interested person may, during the period in which the publications in question are made, raise an opposition in the form of observations and the presentation of information or documents relating to the patentability of the invention. In the case of patents, the opposition may be based on a previous patent, on a patent application already published or on any other form of proof which includes information on the invention that has been made available to the public prior to the application.
- 75. Once the period of publication has elapsed without any opposition being raised, or if the opposition has been considered unfounded, the decision to grant a patent is published and subsequently the patent registration certificate is issued. Should the opposition be proven, a new substantive examination of the application is carried out in order to establish whether the conditions of patentability are satisfied.

Section 61(1) of Patents Act.

Section 27(3) of Patents Act.

INDIA

- 76. The Indian Patent Act provides both pre-grant and post-grant opposition. Where an application for a patent has been published but a patent has not been granted, any person may, in writing, lodge an opposition with the Controller against the grant of a patent.⁵¹ The opposition may be filed on the following grounds together with supporting evidence and a request for hearing, if so desired:
 - (i) the applicant or the person under or through whom he claims wrongfully obtained the invention or any part thereof from him or from a person under or through whom he claims;
 - (ii) the claimed invention has been published before the filing date (priority date) in a specification of an application filed in India on or after January 1, 1912, or in any other documents in India or elsewhere, provided that the disclosure does not fall under the grace period exception as contained in Chapter VI;
 - (iii) the claimed invention is claimed in a claim of a complete specification published on or after the filing date (priority date) of the applicant's claim and filed in pursuance of an application for a patent in India before the filing date (priority date) of the applicant's claim;
 - (iv) the claimed invention is publicly known or publicly used in India before the filing date (priority date). Where a claimed invention is a process invention, it shall be deemed to be publicly known or publicly used in India before the filing date (priority date) of the claim if a product made by that process had already been imported in India before that date, except where such importation has been for the purpose of reasonable trial or experiment only;
 - (v) the claimed invention is obvious and clearly does not involve any inventive step, having regard to the published matters referred to in (ii) or having regard to what was used in India before the filing date (priority date);
 - (vi) the subject of the claimed invention is neither an invention within the meaning of the Act nor patentable under the Act;
 - (vii) the complete specification does not sufficiently and clearly describe the invention or the method by which it is to be performed;
 - (viii) the applicant has failed to disclose the information required by Section 8 of the Act (information regarding corresponding foreign applications) or has furnished false information;
 - (ix) where priority of convention application is claimed, the application was not filed within 12 months from the priority date of first application;
 - (x) the complete specification does not disclose or wrongly mentions the source of geographical origin of biological material used for the invention;
 - (xi) the claimed invention in the complete specification is anticipated having regard to the knowledge, oral, or otherwise, available within any local or indigenous community in India or elsewhere.
- 77. According to Rule 55(1A), no patents shall be granted before the expiry of a period of six months from the date of publication of the application. In other words, third parties have at least

⁵¹ Section 25(1) of the Patent Act 1970.

six months from the publication date of the application to file a pre-grant opposition. If the Controller is of the opinion that the application should be refused or be amended, he shall notify that effect to the applicant together with a copy of the opponent's documents. In response, the applicant may file his statement and evidence in support of his application within three months from the date of the above notice from the Controller. On consideration of the statement and evidence from both parties, the Controller would decide whether a patent should be granted or not.

- Once a patent is granted, third parties have another opportunity to file an opposition.⁵² 78. Such opposition can be filed by any interested person before the expiry of a period of one year from the date of publication of grant of a patent based on the same grounds as described in paragraph 4576. The Controller shall notify the patentee where such notice of opposition was submitted.⁵³ The opponent shall send a written statement setting out the nature of the opponent's interest, the facts upon which he bases his case and relief which he seeks and evidence, if any, along with notice of opposition and shall deliver to the patentee a copy of the statement and evidence, if any.⁵⁴ The patentee is given an opportunity to respond to the opponent's claim and to submit any evidence supporting the patent within two months from the date of receipt of the copy of the opponent's statement and evidence. The patentee shall also send a copy of his response to the opponent. If the patentee does not contest within the above two months period, the patent shall be deemed to have been revoked.⁵⁵ Once the opponent received a copy of the response made by the patentee, he may, within one month, submit evidence strictly confined to matters in the patentee's evidence, and shall deliver to the patentee a copy of such evidence.⁵⁶
- 79. The post-grant opposition is examined by an Opposition Board consisting of three members. It examines all documents and evidence submitted, and submits its recommendations to the Controller. On receipt of the recommendation and after giving the patentee and the opponent an opportunity to be heard, the Controller shall order either to maintain or to amend or to revoke the patent.⁵⁷ The controller shall not take into account any personal document or secret trial or secret use when determining the compliance with (iv) and (v) in paragraph 4576.
- 80. Section 26 of the Patents Act provides specific rules for the case where the opposition was successful on the grounds that the claimed invention was wrongly obtained from the opponent (see item (i) in paragraph 4576 above). In such a case, the Controller may decide that the patent should be amended in the name of the opponent. Similarly, where a part of the invention described in the specification is wrongly obtained from the opponent, the Controller may decide that the specification be amended by the exclusion of that part of the invention.
- 81. The decision of the Controller regarding pre-grant opposition and post-grant opposition may be appealed to the Intellectual Property Appellate Board within three months from the date of the decision, unless the Appellate Board allows another timeframe in accordance with its rules. However, in case where a patent is granted by the Controller after refusing pre-grant opposition, in such circumstances, the decision of the Controller is not appealable before Intellectual Property Appellate Board but a writ petition can be filed in the High Court against such decision.

Section 25(2) of the Patents Act 1970.

Section 25(3) of the Patents Act 1970.

Rule 57 of the Patents Rules 2003.

⁵⁵ Rule 58(2) of the Patents Rules 2003.

⁵⁶ Rule 59 of the Patents Rules 2003.

Section 25(4) of the Patents Act 1970.

PAKISTAN

- 82. The Patent law of Pakistan provides pre-grant opposition and post-grant revocation mechanisms, both conducted before the patent office. Under Section 23 of the Patents Ordinance 2000⁵⁸, at any time within four months from the date of advertisement of the acceptance of a complete specification, any person may give a notice of opposition to the Controller to the grant of a patent on any of the following grounds:
 - (i) the applicant for the patent obtained the invention or any part thereof from him or from the person of whom the opponent is the legal representative, assignee, agent or attorney;
 - (ii) the invention is not a patentable invention within the meaning of the Patent Ordinance;
 - (iii) the specification does not disclose the invention in a manner clear and complete enough for it to be carried out by a person skilled in the art;
 - (iv) the claims are not clear or extend beyond the scope of the disclosure in the complete specification as originally filed;
 - (v) the complete specification describes or claims an invention other than that described in the provisional specification and such other invention either forms the subject of an application made by the opponent for a patent, which, if granted, would bear a date in the interval between the date of the application and the leaving of the complete specification, or has been made available to the public by publication in any document in that interval.
- 83. Upon receiving a notice of opposition from the interested person, the Controller shall send the notice of the opposition to the applicant, and shall, before deciding the case, give the applicant and the opponent an opportunity of being heard. In concluding the argument of both parties, the opposition is decided by the Controller of Patents.
- 84. According to Section 50 of the Patents Ordinance 2000, the Controller of Patents exercises powers of Civil Court in opposition proceedings. An appeal can be filed against the decisions of the Controller of Patents with the High Court under Section 69 of the Patent Ordinance 2000, to be filed within 90 days. If no appeal is filed with the High Court within 90 days, the patent is sealed and granted upon the final determination of the opposition proceedings.
- 85. In addition to the pre-grant opposition mechanism, a system of revocation of patents by the Controller is provided for under Section 47 of the Patents Ordinance 2000, according to which at any time within twelve months after the sealing of a patent, any interested person who did not oppose the grant of the patent may apply to the Controller for an order revoking the patent on any one or more of the grounds upon which the grant of the patent could have been opposed, provided that when an action for infringement, or proceedings for the revocation, of a patent are pending in any court, an application to the Controller under this section shall not be made except with the leave of the court.
- 86. Where a request for revocation is made under Section 47, the Controller shall give notice to the patentee and shall give to the person requesting such revocation and the patentee an opportunity of being heard before deciding the case. If the Controller is satisfied that any of the grounds are established, he may order that the patent shall be revoked either unconditionally or

Patents Ordinance 2000, as amended by Patents Ordinance 2002.

unless within such time as may be specified in the order the complete specification is amended to his satisfaction.⁵⁹

87. According to the Intellectual Property Organisation of Pakistan, the number of oppositions received in 2007 was 33, in 2008 - 199, in 2009 - 246 and 2010 - 129. 60

PORTUGAL

- 88. Portuguese law provides for a pre-grant opposition procedure. As provided by Article 17 of the Industrial Property Code of Portugal⁶¹, the time limit for submitting oppositions is two months from the publication of the application in the Industrial Property Bulletin.⁶² The patent applicant may reply to the opposition within two months from the notification. During the time limits established above and on justified request by the interested party, the Institute of Industrial Property of Portugal (INPI) may grant a single extension of one month for the submission of the opposition and the reply. In the latter case, the opposing party shall be notified.
- 89. The opposition must be filed in writing and shall include a reference as to which patent application is opposed and the reasons on which the opposition is based. If the INPI receives such opposition, the patent applicant has the opportunity to submit comments on that opposition.
- 90. To file an opposition, the opponent has to pay the opposition fee and if the patent applicant wishes to reply to an opposition, it is also necessary to pay a fee (50,70 €, if submitted through online services, or 101,40 € when submitted in paper form, in both cases).
- 91. The substantive examination phase starts after the opposition phase. If an opposition was submitted, it will be considered by the examiner in the analysis of the patentability criteria (novelty, inventive step and industrial applicability). The conclusion of the examination process is the notification of grant, refusal, or partial grant, issued accordingly, and is communicated both to the patent applicant and the opponent. These decisions are subject to appeal at the Lisbon Commercial Court, within two months that follow the publication of the decision in the Industrial Property Bulletin. The total number of oppositions filed from 2005 to 2011 is 29.⁶³

REPUBLIC OF MOLDOVA

92. A post-grant opposition procedure before the State Agency on Intellectual Property (AGEPI) is provided in the Republic of Moldova. According to Article 57 of the National Law on the Protection of Inventions, ⁶⁴ within six months from the publication of the mention of the grant of the patent, any person may give a notice of opposition to the AGEPI to the patent in question, specifying, *inter alia*, the grounds on which the opposition is based, as well as an indication of the evidence and arguments presented in support of those grounds. A notice of opposition shall be examined within three months by the AGEPI division which took the decision to grant the patent.

Section 47 of the Patents Ordinance 2000.

Further statistical data on opposition in Pakistan is available in the Annex to this document.

Industrial Property Code approved by Decree-Law 36/2003 of March 5, 2003 and last amended by Law 16/2008 of April 1, 2008.

The publication of the application is made 18 months after the date of its submission to the National Institute of Industrial Property (Article 66 of the Industrial Property Code).

The number of oppositions covers patent and utility model applications. The statistical data is available in the Annex to this document.

No. 50-XVI of 07.03.2008, in force from October 4, 2008.

- 93. An opposition shall only be filed in writing and on the following grounds:
 - (i) the subject matter of the patent is not patentable within the meaning of Articles 6 to 11;⁶⁵
 - (ii) the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art;
 - (iii) the subject matter of the patent extends beyond the content of the application as filed, or, if the patent was granted on a divisional application or on a new application filed by non-entitled persons, beyond the content of the earlier application as filed.
- 94. The opposition filed shall have suspensive effect. It shall not be deemed to have been filed until the opposition fee has been paid.
- 95. If it is found that the opposition is admissible, the division of AGEPI which issued the decision shall examine, in accordance with the provisions of Article 57 of the Law, whether at least one ground for opposition under Article 57, paragraph (2), of the Law, prejudices the grant of the patent. If the opposition is admissible, the patent applicant shall be notified of the opposition filed and shall be invited to file his observations and to amend, where appropriate, the description, claims and drawings within a period of two months. Any observation and amendments filed by the applicant shall be communicated to the opponent who shall reply within a period of two months. ⁶⁶
- 96. The examiner may require from the opponent or patent applicant additional information necessary for examination. Any notification made during the examination of the opposition and all replies thereto shall be communicated to all parties.
- 97. Where appropriate, during the opposition procedure, AGEPI shall carry out an additional documentary search and shall draw up a search report on a form approved by AGEPI. A reexamination report shall be drawn up on the basis of the opposition examination results which shall be sent to all parties.
- 98. Where it is revealed that the maintenance of the decision to grant the patent is possible by way of amendments, the patent applicant shall be invited to make any amendments or to submit his own amended version of the description and claims, without extending beyond the content of the original application.
- 99. If the AGEPI division which took the decision to grant the patent is of the opinion that at least one of the grounds for opposition referred to above prejudices the maintenance of the patent, it shall revoke the respective decision. Otherwise, it shall reject the opposition. If AGEPI is of the opinion that, taking into consideration the amendments made by the applicant during the opposition proceedings, the patent and the invention to which it relates meet the requirements of the law, it shall decide to maintain the decision to grant the patent as amended. ⁶⁷

Article 6 - patentable inventions, Article 7- exceptions to patentability, Article 8 – novelty, Article 9non-prejudicial disclosure, Article 10- inventive step, Article 11- industrial application.

Rule 332 of the Regulations on the Procedure of Filing and Examination of a Patent Application and of Grant of a Patent, approved by Government Decision of the Republic of Moldova No. 528 of 01.09.2009.

Article 57 of the National Law on the Protection of Inventions.

- 100. If a patent is amended, the AGEPI shall, after the payment of the prescribed fee, publish a new specification of the patent containing the description, the claims and, as the case may be, any drawings, in the amended form.
- 101. Any person adversely affected by a decision taken by the respective division of the AGEPI may appeal with the Appeals Board of the AGEPI within 2 months after the date of notification of the decision and shall contain the grounds for appeal.
- 102. Since the national Law No. 50-XVI of 07.03.2008 on the Protection of Inventions entered into force (see footnote 63), only one opposition has been filed.

SPAIN

- 103. The Spanish Law on Patents⁶⁸ provides for opposition procedures for utility models and patents filed in accordance with the grant procedure subject to preliminary examination. As regards the opposition procedure for patents, within three months following the publication of the prior art search report, the applicant may request an examination as to sufficient description, novelty and inventive step of the subject matter of the patent application. During the two months following the publication of the request for preliminary examination in the *Official Industrial Property Gazette*, any interested party may oppose the grant of the patent, citing the fact that any of the requirements for such grant are not satisfied. The written opposition submission must be accompanied by appropriate supporting documents. However, the lack of the applicant's right to file the patent, which should be claimed before the common courts, may not be claimed.
- 104. The Spanish Patent and Trademark Office will notify the outcome of the examination and forward the oppositions submitted to the applicant. Where no opposition has been submitted and the examination has found that none of the requirements is lacking, the Spanish Patent and Trademark Office will grant the patent.
- 105. Conversely, in cases where oppositions have been submitted, or where the preliminary examination carried out by the Spanish Patent and Trademark Office has found that one of the requirements for the grant of the patent is not satisfied, the applicant may remedy the formal defects claimed in the application, amend the claims, if the applicant so wishes, and respond by submitting allegations he considers appropriate, within two months.
- 106. Where the applicant fails to respond to the objections raised by the Spanish Patent and Trademark Office or by third parties, the patent should be totally or partially refused. In other cases, the Spanish Patent and Trademark Office, by means of a substantiated decision, will decide as to the total or partial grant, once it has received the applicant's response. Where the decision finds that one of the formal requirements is not satisfied or that the invention is not patentable, the Spanish Patent and Trademark Office will grant the applicant a further period of one month to remedy the defect or make observations which he considers appropriate, and will issue a final decision on the grant of the patent.
- 107. The number of oppositions submitted in relation to patents filed according to the general grant procedure subject to preliminary examination is less than those filed as utility models (i.e., less than ten per cent).

Law No. 11/1986, of March 20, on Patents and its Implementing Regulations, approved by Royal Decree No. 2245/1986, of October 10.

SWEDEN

- 108. The Swedish Patents Act provides for a post-grant opposition system. Sections 24 and 25 of the Swedish Patents Act state that anyone except the patent owner can file an opposition regarding a patent in Sweden within nine months from the day the patent was granted. If the Swedish Patent and Registration Office receives such an opposition, the patent owner will have the possibility to comment on that opposition. If the opposition is withdrawn, the Swedish Patent and Registration Office can examine the opposition anyway, if justified. 69
- 109. If the Swedish Patent and Registration Office finds that the patent has been granted despite the fact that the invention lacked novelty or lacked inventive step, or the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, or the subject-matter of the patent extends beyond the content of the application as filed, the patent will be revoked. If the patent owner during the opposition procedure makes amendments so that there is no hindrance against the grant of a patent, the patent is maintained as amended.
- 110. The total number of oppositions filed with the Swedish Patent and Registration Office from 2005 to 2010 is 219. Of the total number, 82 decisions revoked the patents, and 60 decisions maintained the patents as amended.⁷⁰

EURASIAN PATENT OFFICE

- 111. The Eurasian Patent Convention provides post-grant revocation rules in relation to Eurasian patents. A Eurasian patent can be revoked by any person, other than the patent owner, by filing a notice of opposition within six months of the date of publication of information concerning the grant of a Eurasian patent.⁷¹ The time period for filing a notice of opposition may not be prolonged.⁷² A right to file a notice of opposition, lost due to lapse of time for filing, may not be restored.⁷³
- 112. The notice of opposition shall be filed in writing, contain a statement of the reasons thereof, and be supported by the payment of the prescribed fee.⁷⁴ The consideration of the opposition proceeding shall be within six months of the date of its receipt by the Eurasian Patent Office (hereinafter referred to as "the Eurasian Office").
- 113. The notice of opposition can state the following grounds for revocation of a Eurasian patent:⁷⁵
 - (i) failure to satisfy the patentability conditions, because the invention:
 - is not novel;
 - does not involve an inventive step;
 - is not industrially applicable;

⁶⁹ Section 24 of the Swedish Patents Act.

Further statistical data from the Swedish Patent and Registration Office is available in the Annex to this document.

Rule 53(1) of the Patent Regulations under the Eurasian Patent Convention, and Rule 1.1 of the Rules for Filing and Examining Opposition Against the Grant of a Eurasian Patent on the Basis of Administrative Revocation of a Eurasian Patent (hereinafter "Rules of Opposition Filing and Examination").

Rule 37(4) of the Patent Regulations.

Rule 39(3) of the Patent Regulations.

Rule 53(5) of the Patent Regulations.

Rule 53(2) of the Patent Regulations and Rule 1.8 of the Rules of Opposition Filing and Examination.

- is not recognized as an invention per se;
- belongs to solutions for which Eurasian patents shall not be granted.
- (ii) the claims include features that did not appear in the Eurasian application as originally filed.
- 114. Each of the above conditions is a separate ground for revocation of a Eurasian patent. However, (i) incorrect indication of the patent owner or inventor in the Eurasian patent; (ii) non-compliance of the subject matter of the specification or drawings with established requirements; and (iii) failure to comply with the requirement of unity of invention are not grounds for administrative revocation of a Eurasian patent.⁷⁶
- 115. If the notice of opposition is filed in compliance with the prescribed requirements,⁷⁷ the Eurasian Office accepts such notice and notifies the opponent that the notice of opposition has been accepted for examination and invites the patent owner to respond to the notice of opposition within a time limit prescribed by the Eurasian Office.⁷⁸
- 116. The patent owner submits to the Eurasian Office his response to the notice of opposition, presenting his arguments against the opponent's claims and may make changes and amendments to the patent.⁷⁹
- 117. The Eurasian Office subsequently sends the response and the changes and amendments submitted by the patent owner to the opponent or, if several notices of opposition were filed, to all opponents. The Eurasian Office can, if it considers necessary, invite the opponent to present his considerations in respect of the response by the patent owner within a time period stated in the communication.⁸⁰
- 118. The examination of the notice of opposition as to substance and a decision on it on behalf of the Eurasian Office shall be performed by a board consisting of at least three examiners, employees of the Eurasian Office, at least two of whom were not involved in the decision to grant the opposed Eurasian patent. When necessary, a legal expert of the Eurasian Office may be included in the board. The chairman of this board shall be appointed from among those examiners who were not involved in the decision to grant the opposed Eurasian patent.
- 119. The board examines the notice of opposition in respect of those grounds for revocation which are supported in the notice. The board is not obliged, but may examine the validity of the patent grant based on other grounds not presented in the notice.⁸¹
- 120. The examination of the notice of opposition as to substance shall be concluded by passing a decision without convening an oral hearing, unless the parties request to hold such a meeting or the Eurasian Office considers such a meeting expedient.
- 121. The administrative revocation procedure may result in a decision by the Eurasian Office to revoke the Eurasian patent, to reject the notice of opposition, or to correct or amend the patent. The Eurasian patent recognized as invalid as the result of a revocation procedure, either entirely

Rule 1.8 of the Rules of Opposition Filing and Examination.

The notice of opposition shall comply with the conditions specified in paragraphs (1), (5) and (6) of Rule 53 of the Patent Regulations, and Section 1 of the Rules of Opposition Filing and Examination.

Rule 3.2 of the Rules of Opposition Filing and Examination.

Rule 3.5 of the Rules of Opposition Filing and Examination.

Rule 3.8 of the Rules of Opposition Filing and Examination.

Rule 4.4 of the Rules of Opposition Filing and Examination.

or in part, is considered void in all Contracting States as from the date of filing of the Eurasian application.⁸²

- 122. The decision on the opposition to the grant of a Eurasian patent is published in the Gazette of the Eurasian Office. In case the opposition resulted in the amendment of a patent, the Eurasian Office publishes the new specification of the Eurasian patent containing the description as such, the claims and the drawings as amended. In the event of an appeal being filed, no acts related to the implementation of the decision on the opposition, including the entry of changes into the Register of Eurasian patents, publication of information on the decision on the opposition in the Eurasian Office Bulletin, shall be performed until a decision is passed on the appeal.
- 123. An appeal against the decision in question may be lodged by any party in the opposition examination with the President of the Eurasian Office within four months of the date of dispatch of the decision. The President of the Eurasian Office examines the appeal and either orders a renewed hearing of the opposition by the board or takes a final decision on the opposition.⁸³

EUROPEAN PATENT OFFICE (EPO)

- 124. The European Patent Convention (EPC) provides a post-grant opposition. European patents granted by the EPO may be opposed by any person within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin and upon the payment of the opposition fee.⁸⁴ The proprietor of the patent is not entitled to file an opposition,⁸⁵ although he may request limitation of his patent under EPC Article 105a.
- 125. Under certain conditions, any third party who proves that proceedings for infringement of the opposed patent have been instituted against him or that the proprietor of the patent has requested him to cease alleged infringement of the patent and that he has instituted proceedings for a court ruling that he is not infringing the patent may, after the opposition period has expired, intervene in the opposition proceedings. Once the notice of intervention has been filed in good time and in due form, the intervention is to be treated as an opposition.
- 126. The notice of opposition must be filed in writing and contain, *inter alia*, a statement of the extent to which the European patent is opposed and of the grounds on which the opposition is based, as well as an indication of the facts and evidence in support of these grounds.⁸⁷
- 127. The Opposition Division of the EPO is responsible for the examination of the opposition against any European Patent. It consists of three technically qualified examiners, and in some cases where the nature of the decision so requires, it may be enlarged by the addition of a legally qualified examiner.⁸⁸
- 128. As provided by Article 100 of the EPC, the opposition can only be based on the following grounds: the subject-matter of the patent is not patentable under Articles 52 to 57 (patentable inventions, exceptions to patentability, novelty, non-prejudicial disclosures, inventive step, industrial application); the invention is not sufficiently disclosed to allow a person skilled in the art to carry it out; and the content of the patent extends beyond the content of the application as

Rule 53(4) of the Patent Regulations.

Rule 53(8) of the Patent Regulations.

Article 99 EPC.

⁸⁵ G 9/93 (OJ 12/1994,891).

Article 105 EPC.

⁸⁷ Rule 76 of the Implementing Regulation to the EPC.

Article 19 EPC.

filed or, if the patent was granted on a divisional application or on a new application filed under Article 61, beyond the content of the earlier application as filed.

- 129. According to Article 101 of the EPC, if the opposition is admissible, ⁸⁹ the Opposition Division shall examine whether at least one ground for opposition under Article 100 prejudices the maintenance of the European patent. During the examination, the Opposition Division invites the parties to file observations on communications from another party or issued by itself. In particular, after the notice of opposition is granted, it is forwarded to the proprietor of the patent, who may reply with observations or amendments to the description, claims and drawings within a time frame set by the Opposition Division. The observations and amendments filed by the proprietor of the patent are then forwarded by the EPO to other parties to the opposition proceeding, and the opponent(s) who are given the opportunity to respond within a specified period. ⁹⁰
- 130. During the opposition, oral proceedings may take place at the request instance of the EPO or at the request of any party to the proceedings. ⁹¹ The oral proceedings are held before the Opposition Division itself. ⁹² They are generally public unless the Opposition Division decides otherwise in particular cases. ⁹³
- 131. Based on all the evidence, the Opposition Division renders a decision. In the event of parity of votes, the vote of the Chairman of the Opposition Division is decisive. ⁹⁴ If the Opposition Division finds that at least one ground for opposition prejudices the maintenance of the European patent, it revokes the patent. Otherwise, it rejects the opposition. If the Opposition Division concludes that, taking into consideration the amendments made by the proprietor of the patent during the opposition proceedings, the patent (and the invention to which it relates) meets the requirements of the EPC, it decides to maintain the patent as amended after certain formal requirements have been fulfilled. If the patent after such amendments do not meet the requirements of the EPC, the Opposition Division revokes the patent. ⁹⁵
- 132. The opposition shall apply to the European patent in all the Contracting States in which that patent has effect. Decisions by Opposition Divisions are appealable by any party to proceedings adversely affected by the decision before the Board of Appeal of the EPO.⁹⁶
- 133. A notice of appeal must be filed at the EPO within two months of notification of the contested decision, and the fee for appeal must be paid. In addition, within four months of notification of the decision, a statement setting out the grounds of appeal must be filed.⁹⁷
- 134. A petition for review by the Enlarged Board of Appeal of a decision of a Board of Appeal may only be filed on the grounds specified by Article 112a(2) of the EPC.
- 135. In 2010, the number of oppositions filed with the EPO against granted patents was 2,770, compared to 2,700 in 2009 and 2,800 in 2008. The opposition rate was 5,2% in 2010, 4.7% in

Rule 77 of the Implementing Regulation to the EPC provides grounds for a rejection of the opposition as inadmissible.

Rule 79 of the Implementing Regulation to Part V of the EPC.

⁹¹ Article 116(1) EPC.

⁹² Article 19 EPC.

These are the cases where "admission of the public could have serious and unjustified disadvantages, in particular for a party to the proceedings" (Article 166 EPC).

⁹⁴ Article 19 EPC.

⁹⁵ Article 101 EPC.

⁹⁶ Article 106 EPC.

⁹⁷ Article 108 EPC.

2009 and 5.32% in 2008. In 2010, 29% of the opposition cases were rejected, 33% led to revocation of patents and 38% to maintenance in amended form.

136. In 2008, oppositions were filed against 2,800 European patents granted by the EPO (in 2007, against 3,300 patents), and 1,980 decisions in opposition cases took effect (in 2007, 2,100 decisions). Per Overall, about 6% of European patents granted are opposed. Of those, about 1/3 are revoked, 1/3 are maintained in amended form, and 1/3 are maintained as originally granted (the opposition is rejected). The opposition rate before the EPO is consistently higher in the closest available proxy for the pharmaceutical sector than it is in organic chemistry and in all sectors (overall EPO average).

VI. RELATED MECHANISMS

A. RE-EXAMINATION SYSTEMS

136. In some countries, a re-examination system is provided as an alternative to the opposition system. For example, the patent law of the United States of America provides two types of re-examination mechanisms. The primary objective of the re-examination is to provide a forum, other than the courts, for challenging the validity of an issued patent. It allows to re-examine a patent in view of new prior art, and to correct a patent which was inadvertently issued. The following paragraphs describe the re-examination systems in Australia Denmark and the United States of America.

Australia

137. Chapter 9 of the Australian Patents Act¹⁰⁰ provides for re-examination of applications for standard patents and granted standard patents under certain circumstances. Re-examination of innovation patents is also provided for under section 101G.

138. The re-examination is instigated at the Commissioner's discretion, upon request by the patentee or any interested person or by the direction of a prescribed court before which the validity of the patent in question is in dispute. The procedure is *ex parte*, *i.e.* the person who requests re-examination has limited opportunity to submit evidence and be heard in the process. The Commissioner will instigate re-examination voluntarily only if an adverse re-examination report will be issued. In contrast, the Commissioner must re-examine where the patentee or third party requests re-examination.

Denmark

139. Section 53b of the Consolidate Patents Act¹⁰¹ provides an administrative re-examination system. A request for re-examination of a Danish patent (national granted patent or validated European patent) may be filed by any person, including the patent holder, after the expiry of the nine month opposition period.

140. If the request for re-examination is filed by a third party, the request must be filed in writing and contain, *inter alia*, a statement of the extent to which the Danish patent is opposed and the

⁹⁸ EPO Annual Report 2008.

Pharmaceutical Sector Enquiry, Preliminary Report (DG Competition Staff Working Paper), 28 November, 2008.

¹⁰⁰ Australian Patents Act 1990.

The Consolidate Patents Act No.91 of January 28, 2009.

grounds on which the request for re-examination is based, as well as the facts and evidence in support of the grounds.

- 141. According to Section 52 of the Consolidate Patents Act, the re-examination can only be based on the following grounds: the subject matter does not fulfil the patentability criteria (industrial applicability, novelty, inventive step), the invention is not sufficiently disclosed to allow a person skilled in the art to carry it out, the content of the patent extends beyond the content of the application as filed or the scope of protection has been expanded after the grant of the patent.
- 142. After a hearing phase of the re-examination procedure, the Opposition Division renders a decision. The result can be to reject the re-examination, to revoke the patent or maintain the patent in amended form.
- 143. If the request for re-examination is filed by the patent holder, it is only necessary that the request explain the desired limitation of patent claims. No statement of grounds or evidence is mandatory. In this case the Danish Patent Office will examine whether the requested limitation is allowable.
- 144. A notice of appeal must be filed to the Danish Board of Appeal within two months of notification of the re-examination decision, and the fee for appeal must be paid.

United States of America¹⁰²

145. The patent law of the United States of America provides two types of re-examination mechanisms.

(i) Re-examination under 35 U.S.C. §302 to §307

- 146. The re-examination procedure is codified in 35 U.S.C. §§ 302-307 (often called "ex parte re-examination"). These provisions were enacted in 1980 in order to resolve patent validity disputes more quickly and less expensively than litigation, permitting courts to defer issues of patent validity to the expertise of the United States Patent and Trademark Office (USPTO). The re-examination proceedings allows anyone, including the patent owner, to file a request for re-examination of any claim of a patent by providing the USPTO with a written request for re-examination accompanied by the fee, the pertinent prior art, and the manner of applying the prior art to the claim(s) at issue. The identity of the real party in interest may be kept confidential, as an attorney representing the real party in interest may file the request. The prior art cited to the USPTO by the requester must consist of patents or printed publications. Unless the person requesting re-examination is the patent owner, he will then be notified by the USPTO of the request for re-examination.
- 147. The USPTO will determine within three months whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, and if so, a re-examination proceeding will be initiated. The USPTO, in making its determination, is not limited to the prior art submitted by the requester, but may also consider other patents and printed publications. ¹⁰⁶ For example, any relevant prior art patents or printed publications

The revision to this chapter was made according to the submission of the USPTO dated August 15, -2011. It does not include information regarding the recent amendments introduced by the America Invents Act.

See 145 Cong. Rec. H6929, H6944 (daily ed. Aug. 3, 1999)

Syntex Inc. v. United States Patent and Trademark Office, 882 F.2d 1570, 1573 (Fed. Cir. 1989).

¹⁰⁵ 35 U.S.C. § 302.

¹⁰⁶ 35 U.S.C. § 303(a).

submitted by a third party that have been included in the official file under 35 U.S.C. §301 (see Chapter VI(2)) may be considered in the re-examination process. The determination that no substantial new question of patentability has been raised is final and non-appealable by both parties. ¹⁰⁷

- 148. Where the USPTO issues an order for re-examination of the patent, the patent owner will be given a period not less than two months from the date the copy of the determination is given to him, within which he may file a statement including any amendments he may wish to propose. Where a patent owner files such a statement, its copy is communicated to the requester. The requester may submit a response to the statement made by the patent owner. If the patent owner decides not to file a statement, the requester may not file any further communications in the proceeding.
- 149. After the time limits for filing the statement by the patent owner and reply by the third party requester have expired, the re-examination procedure will be conducted in a manner similar to that of the initial examination process. In any re-examination proceeding, the patent owner is permitted to propose any amendment to his patent and a new claim to distinguish his patent from the prior art cited, although the scope of the claims may not be enlarged. 109
- 150. Once the USPTO renders a decision, the patent owner may appeal an adverse determination to the Board of Patent Appeals and Interferences (BPAI). A further appeal can be made to the Court of Appeals for the Federal Circuit or to the District Court (for the District of Colombia). The ex-parte re-examination requester, other than the patent owner, has no right to participate in either appeal.
- 151. According to the latest data provided by the USPTO, there have been 11,604 *ex parte* re-examinations applications filed with the USPTO since the start of *ex parte* re-examination in January 1981 up to June 30, 2011. Of those, 33 % were filed by the patent owner, 66% by other member of public and 1% by order of the Commissioner. The highest number of re-examination requests concerned patents in electrical operation (37%), mechanical operation (34%) and chemical operation (27%). 92% of those requests were granted and 8% were denied. 111
- 152. In 2008, 680 requests for ex parte re-examination were filed with USPTO (in 2007, 643 requests). The number corresponds to about 0.43% of the number of patents issued in a given year. The highest number of re-examination requests, in 2008, concerned patents in the electrical field (305 requests), followed by the mechanical field (237 requests). Of the total number of requests filed in 2008, 626 requests were granted and 40 requests were denied.

¹⁰⁷ 35 U.S.C. § 303(c).

¹⁰⁸ 35 U.S.C. § 304.

¹⁰⁹ 35 U.S.C. § 305.

¹¹⁰ 35 U.S.C. § 306.

Other statistical data submitted by the USPTO on *ex parte* reexamination filing is available in the Annex to this document.

⁴¹² USPTO Performance and Accountability Report, Fiscal Year 2008.

(ii) Inter Partes Re-examination

- 152. Optional *inter partes* re-examination is codified in 35 U.S.C. §§ 311-318.¹¹³ 114 The primary objective of the *inter partes* re-examination procedure is to reduce costly patent litigation in US district courts by providing an expanded means for third parties to challenge the validity of a patent.¹¹⁵ Compared with the *ex parte* re-examination procedure above, the following major differences are found in the *inter partes* re-examination procedure. First, *inter partes* re-examination may only be filed by a third party, but not by the patent owner. Second, the *inter partes* procedure allows the third party requester to fully participate in the proceedings. He receives any document filed by the patent owner and a copy of all communications sent from the Office to the patent owner in relation to the *inter partes* re-examination, and has an opportunity to file comments on the issues raised by the patent owner or the Office. In the *ex parte* re-examination procedure, an opportunity for the third party re-examination requester to submit a comment is given only during a limited period and under certain conditions.
- 153. *Inter partes* re-examination may be initiated by any third party requester at any time on the basis of prior art consisting of patents and printed publications. Such a request shall include the identification of the real party in interest standing behind the request, payment of the established fee, the cited prior art, and a statement regarding the manner in which the prior art should be applied to the claims of the patent. 117
- 154. Within three months after the filing of the request, the USPTO will determine whether a substantial new question of patentability affecting any claim of the patent concerned is raised by the request, with or without consideration of other patents or printed publications. The determination that no substantial new question of patentability has been raised is final and non-appealable. In a substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question of patentability has been raised in the substantial new question o
- 155. If it is found that a substantial new question of patentability affecting any claim of the patent is raised, the USPTO issues an order for *inter partes* re-examination of the patent. *Inter partes* re-examination is conducted according to the procedures established for initial examination in that the patent owner is permitted to propose any amendment to his patent and a new claim to distinguish his patent from the prior art cited, although the scope of the claims may not be broadened. Any document filed by either the patent owner or the third party requester shall be communicated to the other party. The third party requester will be copied by the USPTO on each communication sent by the USPTO to the patent owner in the proceeding.
- 156. In *inter partes* re-examination, the third party requester has an opportunity to file written comments within thirty days after the date of service of the patent owner's response to an action of the Office. Each time when the patent owner files such response, the third party requester has one opportunity to make comments. These comments may address issues raised by the USPTO, as well as issues raised by the patent owner.¹²¹

¹¹³ 35 U.S.C. §§ 311-318.

Both, the ex parte re-examination and the inter partes re-examination, are available for patents issued from applications filed on or after November 29, 1999. For patents issued from an application filed prior to November 29, 1999, the statutory inter partes re-examination option is not available, and only the ex parte re-examination is available.

¹⁴⁵ Cong. Rec. E1788, at E1789-90.

¹¹⁶ 35 U.S.C. § 311(a).

¹¹⁷ 35 U.S.C. § 311(b).

¹¹⁸ 35 U.S.C. § 312(a).

¹¹⁹ 35 U.S.C. § 312(c).

¹²⁰ 35 U.S.C. § 314.

¹²¹ 35 U.S.C. § 314(b)(2).

157. Either party may appeal an adverse final decision of the USPTO to the BPAI. A further appeal is possible to the Court of Appeals for the Federal Circuit. The patent owner may be a party to any appeal initiated by a third party requester, and *vice versa*.¹²² In addition, the patent owner has the option of obtaining a stay of pending litigation involving a question of validity of the same patent after an order for *inter partes* re-examination has been issued by the USPTO.¹²³ A third-party requester is estopped from asserting at a later time, in any civil action the invalidity of any claim that was determined to be valid and patentable on any ground which the third party requester raised, or could have raised, during the *inter partes* re-examination proceedings.¹²⁴ The estoppel provision, however, does not prevent the assertion of invalidity based on newly discovered prior art unavailable to the third party requester and the USPTO at the time of the *inter partes* re-examination proceedings.¹²⁵

158. In 2008, 168 requests for *inter partes* re-examinations were filed with the USPTO (in 2007, 126 requests). Of those, 142 requests were granted, and 8 requests were denied. The number corresponds to about 0.10% of the number of patents issued in that year. The highest number of re-examination requests, in 2008, concerned patents in the electrical field (67 requests), followed by the mechanical field (73 requests).

158. The total number of requests filed since the start of *inter partes* re-examination in November 1999 till June 30, 2011 was 1286. The highest number of re-examination requests concerned electrical operation (53%) and mechanical operation (29%). Among the total *inter-partes* re-examination requests, 95% were granted and 5% were denied. 127

(iii) A Substantial New Question of Patentability

- 159. Both *ex parte* and *inter partes* re-examination procedures are ordered only when there is "a substantial new question of patentability" in at least one claim of the patent. If there is no such "question", no re-examination can be initiated. The meaning and scope of the "substantial new question of patentability" is developed through case law.
- 160. A prior art patent or printed publication raises a substantial question of patentability where there is a substantial likelihood that a reasonable examiner would consider the prior art patent or printed publication important in deciding whether or not the claim is patentable. If the prior art patents and/or publications are considered important, then the examiner should find that "a substantial new question of patentability" exists.
- 161. However, if the same substantial question of patentability has already been decided previously, re-examination will not be proper. For example, if the examiner finds that the additional prior art patents or printed publications are merely cumulative to similar prior art already fully considered in a previous examination of the claim, there is no "substantial new question of patentability".

¹²² 35 U.S.C. § 315.

¹²³ 35 U.S.C. § 318.

These provisions are aimed at preventing *inter partes* re-examination proceedings from being used to harass patent owners (see the submission of the USPTO on the SCP electronic forum website).

¹²⁵ 35 U.S.C. § 315(c).

USPTO Performance and Accountability Report, Fiscal Year 2008.

Other statistical data submitted by the USPTO on *inter partes* reexamination filing is available in the Annex to this document.

- 162. Accordingly, for "a substantial new question of patentability" to exist, it is necessary that:
 - (i) the prior art patents and/or printed publications raise a substantial question of patentability regarding at least one claim. This means that the teaching of the prior art is such that a reasonable examiner would consider the teaching to be important in deciding whether or not the claim is patentable; and
 - (ii) the same question of patentability as to the claim has not been decided by the Office in a previous examination or pending reexamination of the patent or in a final holding of invalidity by the Federal Courts in a decision on the merits involving the claim.

It is not necessary for the submitted prior art to form a "prima facie" case of unpatentability. A "substantial new question of patentability" as to a patent claim may exist even if the examiner would not necessarily reject the claim as either anticipated by, or obvious in view of, those prior art patents or printed publications.

B. SUBMISSION OF INFORMATION BY THIRD PARTIES.

(i) Rationale and objectives

- 163. In countries where a patent application is published before the grant of the patent, third parties are in a position to analyze the claimed invention contained in the published patent application before the grant of the patent or the refusal of the patent application. In order to assist a substantive examiner to examine the patentability of the claimed invention, in some countries, third parties may submit prior art information which is relevant to such determination of patentability. In general, the fact that information is submitted by a third party and the content of such information are made available to the public. The objective of such mechanism is, similar to the pre-grant opposition system, to increase the validity of granted patents through contributions from third parties having good knowledge of the prior art technology concerned.
- 164. The third party observations system, however, is different from the pre-grant opposition system in many aspects, although it varies from one country to the other. It is a procedure under which the third party who submitted the information cannot participate in the subsequent review procedure. The submission of the relevant information does not trigger any specific review process (although an examiner may take into account the submitted information, if appropriate), and the information will be simply included in the file which can be consulted by the public. In many countries, there is no time limit for third parties to submit relevant information. The anonymous submission of information is allowed in certain countries. This could help third parties to submit prior art information even if they have business relationship with the applicant and therefore, are unwilling to disclose their identities. Further, in some countries, the grounds for the submission of information may be limited by certain requirements.
- 165. Theoretically, it is possible to introduce such a system in a patent office that does not conduct substantive examination. The prior art information submitted by a third party will be made available to the public upon the publication of the patent, and it can be used by any party during the post-grant revocation proceedings. For that reason, in some countries, third parties may also submit prior art information to the patent office anytime during the post-grant phase. The submitted information will be included in the official file (dossier) which is accessible to the public.
- 166. The submission of information relevant to patentability by third parties is a simple, inexpensive (often free of charge) and informal way to publicly question the validity of a patent. On the other hand, due to its informal nature, the submitter of the information cannot participate in and influence the review process. Whether the information submitted would be fully

considered during the review process depends on <u>the</u> examiner who conducts the substantive examination and on the party requesting the opposition/revocation of the patent concerned.

167. The possibility of introducing third party observations in the Patent Cooperation Treaty (PCT) system has been explored by the PCT Working Group. The draft PCT Roadmap suggesteds that a system that alloweds third party observations on novelty and inventive step which will-would be made available to the International Preliminary Examining Authority and designated Offices be developed by January 2011 (see document PCT/WG/2/3, Annex I, paragraph 5). At the second session of the PCT Working Group, held from May 4 to 8, 2009, several delegations stated that more discussions were needed on the possible details of such a third party observations system, including whether the applicant should be entitled to comment on any such third party observations and the possible need for translations of such observations. One delegation stated that it wished to reserve its position on the proposal to set up a system allowing for the submission of third party observations, noting the possible impact on the pre-grant opposition system existing under its national law (see document PCT/WG/2/14, paragraph 58).

168. Meanwhile, work has begun on the implementation of a third party observation system, broadly in line with the proposals set out in the Annex to Circular C. PCT 1288 and taking into account the comments received in response to that Circular. While the fourth session of the PCT Working Group, held from June 6 to 10, 2011, supported the introduction of the system, it noted a number of concerns with regard to specific features of the system which the International Bureau would further consider in the implementation of the system. The pilot will be closely monitored, in particular with regard to possible abuses. The service is expected to start in early 2012.

(ii) National/Regional laws

169. The following paragraphs provide information regarding third party observation mechanisms contained in some national/regional laws.

Australia

170. Australia allows third party observations under Section 27 of the Patents Act¹²⁸ in relation to standard patents. Under this provision, a person may, within the prescribed period after a complete specification becomes open to public inspection, notify the Commissioner, in accordance with the Regulations, that the person asserts, for reasons stated in the notice, that the invention concerned is not a patentable invention because it does not comply with the requirements of novelty, inventive step and usefulness.

171. The Commissioner must inform the applicant for the patent in writing of any matter of which the Commissioner was notified and send the applicant a copy of any document accompanying the notice. The Commissioner must otherwise consider and deal with a notice in accordance with the Regulations. The notice and any document accompanying it are open to public inspection.

¹²⁸ Patents Act 1990.

In addition, Section 28 of the Patents Act allows third party observations in relation to innovation patents.

China

172. Rule 48 of the Implementing Regulations of the Patent Law states that any person may, from the date of publication of an application till the date of announcing the grant of a patent, submit his observations on an application which is not in conformity with the provisions of the Patent Law. The observations shall be submitted to the Patent Administration Department with reasons of non-compliance with the provisions.

Denmark

173. Rule 43 of the Order on Patents and Supplementary Protection Certificates states that any person may provide information or observations of relevance for the examination of a patent application. No particular grounds are to be specified.

Finland

174. Third parties may file a communication which is of importance for the examination of the application with the Patent Office. There is no fee and no particular grounds are to be specified. The Office shall notify the party that submitted the communication of the possibility of filing an opposition if a patent is granted. ¹³⁰

Japan

175. Rules 13*bis* and 13*ter* of the Regulations under the Japanese Patent Law provides that any person may submit information relating to patentability of claimed inventions contained in a patent application or a granted patent to the Commissioner of the Japan Patent Office (JPO). Such information can be submitted anonymously. The content of the submitted information is open to the public inspection. No fee is required for the submission of this information.

176. The information that third parties may submit shall be on the following grounds, which shall be substantiated by written evidence:

- the claimed invention is not patentable subject matter or it does not meet the requirement of novelty, inventive step or industrial applicability;
- double patenting or the claimed invention is contained in an application filed earlier but published later than the filing date of the application/patent concerned (noncompliance with Article 29bis or 39(1) to (4) of the Japanese Patent Law);
- the description requirement has not been met (non-compliance with Article 36(4) or (6) (except (6)(iv)) of the Japanese Patent Law);
- the patent application was amended in a manner that new matter going beyond the scope of the disclosure at the time of the filing date has been included (non-compliance with Article 17 bis(3) of the Japanese Patent Law);
- the scope of the Japanese translation of an application filed in a foreign language goes beyond the scope of the application as filed;
- the patent was corrected in a manner not in compliance with Article 126(1), *proviso*, (3), (4) or (5), or Article 134*bis*, *proviso*.

¹³⁰

- 177. The submitted information will be notified by the JPO to the applicant concerned (or the patentee concerned). Upon request, it is possible to obtain a feedback as to whether the submitted information has been utilized by an examiner for the purpose of substantive examination or not.
- 178. In addition to paper submissions, relevant information may be submitted on-line to the JPO. In 2007, 7,487 submissions were made in total, and 76% of them were utilized by examiners. Inspired by the Peer Review Prior Art pilot project conducted by the USPTO (see below), the JPO has started a Community Patent Review pilot since July 2008. The pilot project has, in general, produced positive results. 132

Mexico

- 179. Article 52 BIS of the Industrial Property Law (LPI) states that within a period of six months, beginning from the date of publication of the patent application in the Official Gazette, the Institute may receive information from any person relating to the issue of whether the application complies with the provisions of Articles 16 (novelty, inventive step and industrial applicability requirements) and 19 (subject matters not considered inventions) of LPI.
- 180. The Institute may treat the said information as technical support documents within the context of the substantive examination of the application, without being obliged to rule on the scope of said information. The Institute shall make the information available to the applicant, in order to allow him, should be consider it necessary, to put forward in written form any arguments that he might deem to be in his interest.
- 181. The submission of information shall not have the effect of suspending the process, nor shall the person submitting the information be attributed the status of interested party, third party or party, and, should the case arise, the actions provided for in Article 78 (nullity) of this Law shall be carried out. To date, no submissions have been made under this provision. 133

Pakistan

182. Under Section 24 of the Patents Ordinance, 2000 and Rule 19 of the Patent Rules, 2003, at any time after the publication of the accepted specification in the Official Gazette, any person can make observations in writing to the Controller on the novelty of the invention giving evidence in support of his observations. The Controller shall consider the observations in the light of the evidence made available to him before the grant of the patent. The person shall not become a party to the proceedings.

Philippines

183. Section 47 of the Intellectual Property Code (Republic Act No. 8293) states that, following the publication of an application, any person may present observations in writing concerning the patentability of the invention. Such observations must be filed in writing and must include a statement, in English or Filipino, of the grounds on which they are based. The person who submitted the observations shall not be a part to the proceedings before the Bureau of Patents. No fee is required to submit observations. Since opposition proceedings before the

¹³¹ JPO Annual Report 2008.

The report is available at: http://www.peertopatent.org/CPR Pilot Report.pdf.

Article 52 BIS is a new provision which entered into force on September 18, 2010.

Manual for Substantive Examination Procedure, Chapter VI.11.

¹³⁵ *Ibid*.

Bureau of Patents are not provided for in the Intellectual Property Code, the third party observation system is considered to be a low-cost way to challenge a potential patent. 136

- 184. According to Section 47, the observations shall be communicated to the applicant who may comment on them. The Patent Office shall acknowledge receipt of such observations and comments and put them in the file of the application to which they relate. The Patent Office will not inform the third party of any further action taken by the Office in response to his observations.¹³⁷
- 185. If the observations relate to alleged prior art other than a document form, for example, from use, such observations should be taken into account only if the alleged facts are either not disputed by the applicant (or proprietor) or established beyond reasonable doubt. Observations received from third parties after the conclusion of proceedings will not be taken into account and will be simply added to the file.

Slovak Republic

- 186. Article 42(1) of the Patent Act¹³⁸ provides that any person may file oppositions on patentability of the subject-matter of an application with the Office after publication of the application. If the oppositions are filed, the Office shall take them into consideration during substantive examination of the application.
- 187. According to Article 42(2) of the Patent Act, persons who have filed oppositions pursuant to paragraph 1 shall not become parties to the application proceedings. However, an applicant shall be notified about oppositions and shall have the right to respond to them.
- 188. According to the data submitted by the Industrial Property Office of the Slovak Republic, there were 2 oppositions filed over 231 published patent applications in 2006, 3 oppositions over 167 patent applications in 2007, 3 oppositions over 181 patent application in 2008, 4 oppositions over 179 patent applications in 2009 and 5 oppositions over 153 patent applications in 2010. 139

Spain

189. According to the general grant procedure of Spain, *i.e.*, the procedure which does not involve preliminary (substantive) examination, ¹⁴⁰ once the continuation of such procedure has been published in the *Official Industrial Property Gazette*, a period of two months is granted to third parties to raise duly reasoned and documented comments on the prior art report (search report). ¹⁴¹ Once the deadline for third parties to submit comments on the prior art report has passed, the written submissions are forwarded to the applicant to set out comments which he considers appropriate on the prior art report, make the comments which he deems relevant to the comments raised by third parties and, if he so desires, to amend the claims, within two months. Independently of the content of the prior art report and of the comments submitted by

¹³⁷ *Ibid.*

¹³⁶ *Ibid.*

Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates and Amendment of Some Acts (The Patent Act).

The statistical data is available in the Annex to this document.

Within three months following the publication of the report on a

Within three months following the publication of the report on prior art (search report), the applicant may express his desire that an examination as to sufficient description, novelty and inventive step will take place or that the grant procedure will continue without examination. In any case, where no preference has been expressed within those three months, the grant procedure will continue without the preliminary examination.

The share of patent applications filed according to the general grant procedure (without preliminary examination), in which comments are submitted by third parties, is less than ten per cent.

third parties, once the deadline for the applicant's comments has passed, the Spanish Patent and Trademark Office will grant the patent, announce this in the Official Industrial Property

Gazette and provide the public with the documents relating to the patent, together with the report on prior art and all the comments relating to such report. In the case where claims have been amended, the public shall be provided with the amended claims, with an indication of the respective date(s) of the amendment.

United Kingdom

- 190. Section 21 of the Patents Act 1977 provides that, where an application for a patent has been published but a patent has not been granted to the applicant, any other person may make observations in writing to the comptroller on the question whether the invention is a patentable invention, stating reasons for the observations. Such other person cannot become a party to any proceedings under the Act before the controller. In other words, apart from the receipt of acknowledgement (see below), he has no right to discuss the matter directly with an examiner or request a notification about the decision taken by the examiner. The observations can be submitted anonymously. No fee is required for the submission of observations.
- 191. Rule 33 of the Patents Rules 2007 provides detailed procedures regarding third party observations. The controller must send to the applicant a copy of the observations on patentability, unless they disparage any person in a way likely to damage such person or are generally expected to encourage offensive, immoral or anti-social behavior. The controller may, if necessary, send to the applicant a copy of any document referred to in the observations. It is recommended that any observations be filed within three months after the application has been published, as a patent may be granted after that period. The observations must be made in writing, and can be filed on paper or electronically. They shall be supported by evidence wherever possible.
- 192. The Office will acknowledge receipt of the submitted observations if contact information of the submitter is available. Where observations were made before the grant of the patent, an examiner will take them into account when deciding upon the patentability of the invention concerned. The observations will be added to the official file, which is available to the public, and a copy of the observations will be sent to the applicant. Even if the observations are received after the grant of the patent, they will be placed in the patent file, and a copy of the observations will be sent to the patentee.

United States of America

(i) Third party submission in published application

- 193. According to 35 U.S.C. § 301, any person may at any time cite to the USPTO, in writing, prior art consisting of patents or printed publications which that person believes to have a bearing on the patentability of any claim of a particular patent. If the person explains in writing the pertinency and manner of applying such prior art to at least one claim of the patent, the citation of such prior art and the explanation thereof will become a part of the official file of the patent. It is possible to submit such prior art information anonymously (upon request, the identity of the submitter will be excluded from the official file and kept confidential).
- 194. In accordance with 37 C.F.R. § 1.99, there is the possibility for third parties to submit patents or printed publications relevant to a pending published patent application. The submission must be filed within two months from the date of publication of the application or prior to the mailing of the notice of allowance, whichever is earlier. If the relevant patents or publications are not in English, an English translation of all the necessary and pertinent parts is

http://www.ipo.gov.uk/types/patent/p-other/p-object/p-observation/p-observation-making.htm.

required. The submission shall not include any explanation of the patents or publications provided, or any other information. The USPTO will not enter such explanation or information if it is included in the submission under 37 C.F.R. § 1.99. The information submitted will be included in the application file. A fee (USD180.00) shall be paid, and the submission is limited to ten total patents or publications.

195. The submitter of the information shall serve a copy on the applicant. In the absence of a request by the USPTO, the applicant, however, has no duty to, and need not, reply to such submission. The submitter of the information will not receive any communication from the USPTO relating to such submission, except where included a self-addressed postcard with the submission to receive an acknowledgement of receipt by the USPTO. The submission of patents and publications relevant to pending patent applications under 37 C.F.R. Section 1.99 can be made only on paper.

(ii) Protest under 37 C.F.R §1.291.

196. In addition to the third party submission in respect of published applications, a protest under 37 C.F.R §1.291 may be filed by a member of the public against a pending application, to challenge the issuance of a patent from the application. In this case, the protester is entitled to provide written comments describing the relevance of publications or other information being submitted as prior art to the claims of the pending application of the patents. However, under 37 C.F.R. 1.291, the protest must be filed before the challenged pending application is published, or if the application is not published, before a Notice of Allowance is issued. Thus, a protest can only take place when the challenger has personal knowledge of the application being filed. The total number of protests filed from 1996 to 2011 is 127.¹⁴³

197. In 2007, the USPTO started a pilot project, "Peer Reviewed Prior Art Pilot", to determine the extent to which the organized submission of documents together with comments by the public will provide useful prior art for examiners. Following a proposal by a group of academic and business professionals, the pilot tests a collaborative, on-line, community process where the public may locate potential prior art information on a dedicated Peer-to-Patent website developed by the Community Patent Review Project of the Institute for Information Law and Policy at New York Law School. The pilot, in particular, analyzes whether such collaborative public review would effectively identify prior art that might not otherwise be found during the ordinary examination process.

198. The community patent review process enables the public to submit prior art information and commentary relevant to the claims of pending patent applications, which have been posted on the Peer-to-Patent website by volunteer applicants. Following the community review process, the top ten references, along with a commentary, are submitted to the USPTO for its consideration. The pilot is limited to the applications in the fields of computer architecture, computer networks, cryptography and security and business methods.

199. The USPTO has lately been evaluating the impact of public input on improving patent quality through the Peer-to-Patent review process. As of October 1, 2009, office actions have been taken with respect to 104 pilot applications. Among those, 21% referred to prior art found by third parties through the Peer-to-Patent review. Among such prior art found by third parties, half of them, however, were also found by examiners independently.¹⁴⁶

A breakdown of data by year is available in the Annex to this document.

Information concerning the Peer Reviewed Prior Art Pilot is available at:

http://www.uspto.gov/patents/init_events/peerpriorartpilotindex.jsp

http://www.peertopatent.org/

http://www.uspto.gov/web/patents/peerpriorartpilot/p2ppie.pdf

European Patent Office (EPO)

200. In accordance with EPC Article 115, in proceedings before the EPO, any third party may present observations concerning the patentability of the invention to which the application or patent relates, once the publication of the European patent application was made. That person may will not be a party to the proceedings before the EPO. No fee is required for the submission of observations.

201. Such observations shall be filed in writing in an official language of the EPO, and state the grounds on which they are based.¹⁴⁷ Documentary evidence and, in particular, publications submitted in support of the arguments may be filed in any language. However, the EPO may request that a translation into one of its official languages be filed; otherwise the evidence will be disregarded.¹⁴⁸

202. The observations made by a third party will be communicated to the applicant (or the patentee), who may comment on them.¹⁴⁹ If they call into question the patentability of the invention in whole or in part, they must be taken into account in any proceedings pending before a department of the EPO until such proceedings have been terminated, i.e. they must be admitted to the proceedings.¹⁵⁰ If the observations relate to alleged prior art available other than from a document, e.g. from use, this should be taken into account only if the alleged facts either are not disputed by the applicant (or the patentee) or are established beyond reasonable doubt.¹⁵¹ Observations received after the conclusion of the proceedings will simply be added to the file.¹⁵² Although the third party is sent acknowledgment of the receipt of his observations, the EPO does not inform him of any further action it takes in response to them.¹⁵³

203. In order to facilitate the fling of third party observations, the EPO has launched a pilot project. As of August 1, 2011, such observations can be filed by filling out an online form on the EPO website. The traditional means of filing (e.g. by letter or fax) will continue to be accepted.

[End of documentAnnex follows]

Rule 114(1) of the Implementing Regulations under the EPC.

EPO Examination Guidelines, Part E, VI.3.

Rule 114(2) of the Implementing Regulations under the EPC.

EPO Examination Guidelines, Part E, VI.3.

¹⁵¹ *Ibid*.

¹⁵² *Ibid.*

¹⁵³ *Ibid.*

STATISTICS ON OPPOSITIONS

AUSTRALIA

	2006/07	2007/08	2008/09	2009/10	2010/11
Re-examination ¹	5	11	18	15	22
Opposition ²	130	109	167	120	143
Applications Filed ³	27594	27979	26259	25443	26473

The re-examination number is third-party requested re-examination only. It does not include re-examinations that are initiated by the Commissioner in other circumstances.

FINLAND

(a) Number of granted patents against which an opposition has been filed in 2006-2010

Year	Number of opposed patents	Number of oppositions filed
2006	29	31
2007	20	21
2008	18	21
2009	24	26
2010	20	23

(b) Decisions taken in oppositions filed in 2006-2010

Year*	Rejection of the opposition	Maintenance in amended form	Revocation of the patent
2006	13	3	10
2007	9	4	5
2008	8	1	6
2009	5	2	4
2010	1	1	0

Refers to the year in which the opposition has been filed, not to the year in which the decision has been taken.

The oppositions numbers relate to Section 59 oppositions only.

The applications filed number does not include provisional filings, but does include both innovation and standard patent applications.

GEORGIA

- 6814 Satisfied appeal concerning invention of semi-rigid collapsible container;
- 8520 The appeal was dismissed;
- 9438/01 Proceedings are terminated;
- 8690 Rejected the appeal;
- 9792 (keyboard) Refused the appeal concerning the invention of;
- 9985 (non-peptide bradyking antagonist and their pharmaceutical compositions) the appeal was upheld;
- 9635 (method of granulation) the appeal was refused;
- 10640 (helicopter main motor aerodynamic aerofoil) refused the appeal;
- 106041 (accumulation) the appeal was rejected.

GERMANY

- 665 oppositions were filed in 2010.
- Opposition proceedings conducted in 2010 were concluded as follows:
 - 75 cases by the abandonment of the patents by the patent owner;
 - 87 cases by the abandonment of the patents by non-payment of annual fee;
 - 278 cases by the revocation of the patents;
 - 538 cases by the decisions to maintain the patents in full or in part.
- Patent owners lodged appeal against the revocation of their patents in 61 cases.
- In 123 cases, appeal was lodged against the decisions of the DPMA to maintain the patents in full or in part.

PAKISTAN

S. No	Year	Accepted cases	Opposition received	Area of Technology	Rate of opposition
1	2007	115	33	Pharma	32.63%
2	2008	577	199		
3	2009	501	246		
4	2010	667	129		

PORTUGAL

Number of oppositions filed at the Portuguese Institute of Industrial Property since the year 2005. Please notice that these oppositions concern patent applications and also utility model applications.

Year	Number of Oppositions
2005	4
2006	6
2007	3
2008	2
2009	2
2010	8
2011	4
Total	29

SLOVAKIA

Year	2006	2007	2008	2009	2010
Number of published applications	231	167	181	179	153
Number of filed pre-grant opposition	2	3	3	4	5

SWEDEN

Year	2005	2006	2007	2008	2009	2010
Oppositions filed	57	42	30	26	31	33
Objection revoked	16	13	17	17	16	15
Patents maintained as amended	9	6	11	13	12	9
Revoked patents	6	20	20	11	17	8

UNITED STATES OF AMERICA

(a) Statistical data on the performance of the USPTO reexamination program

Inter Partes Reexamination Filing Data - June 30, 2011

			<u>Inter Par</u>	<u>tes</u> Reexamir	nation Fill	ing Data – Jun	e 30, 20	11	
1.	Total requests filed since start of <i>inter partes</i> reexam on 11/29/991286 ¹⁵⁴								
2.	Number of filings by discipline								
	a. b. c. d.	b. Electrical Operationc. Mechanical Operation						224 676 371 15	17% 53% 29% 1%
3.	Ann	ual Reexa	m Filings						
		scal Yr. 2000 2001 2002	No. 0 1 4	Fiscal Yr. 2003 2004 2005	<u>No.</u> 21 27 59	Fiscal Yr. 2006 2007 2008	No. 70 126 168	Fiscal Yr. 2009 2010 2011 YTD	<u>No.</u> 258 281 271
4.	Nun	nber knowr	n to be in	litigation				910	71%
5.	Dec	isions on re	equests.						1155
	a.	No. gran	ted					.1099	95%
		(1) By ex (2) By D		n petition)				1092 7	
	b.	No. not g	granted					53	5%
		(1) By ex (2) Reex		ted				48 5	
6.	Ove	rall reexan	nination p	endency (Fil	ing date t	to certificate is:	sue date	·)	
	a. b.	Average Median p					36.6 (33.0 (
7.	Tota	al <i>inter part</i>	tes reexa	mination cert	ificates is	sued (1999 – _I	oresent)		278
	a. b. c.	Certificat	es with a	II claims conf II claims cand laims change	celled (or	disclaimed)		35 123 120	13% 44% 43%

Of the requests received in FY 2011, 3 requests have not yet been accorded a filing date, and 5 requests have had preprocessing terminated, for failure to comply with the requirements of 37 CFR 1.915. See Clarification of Filing Date Requirements for *Ex Parte* and *Inter Partes* Reexamination Proceedings, Final Rule, 71 Fed. Reg. 44219 (August 4, 2006).

Ex Parte Reexamination Filing Data – June 30, 2011

1	Tota	d roquosto f	م ممانه امان	tort of av no	rto roover	m on 07/01/01	Ī	,	14604 ¹⁵⁵
1.	1018	ii requests t	lied since s	tart of <i>ex pai</i>	te reexar	n on 07/01/81	l	<i>′</i>	11604
	a. b.	By patent	owner nember of p	oublic				3761 7677	33% 66%
	C.	•	of Commiss					166	1%
2.	Nun	nber of filing	s by discip	line					
	a.	Chemical	Operation					3180	27%
	b.	Electrical (Operation .	_				4323	37%
	c. d.	Design Pa	al Operation atents	i)				3922 179	34% 2%
3.	Ann	ual <i>Ex Parte</i>	e Reexam F	Filings					
	Fis	scal Yr.	No.	Fiscal Yr.	<u>No.</u>	Fiscal Yr.	No.	Fiscal Yr.	No.
		1981 78 1982	3 (3 mos.) 187	1989 1990	243 297	1997 1998	376 350	2005 2006	524 511
		1983	186	1990	307	1999	385	2007	643
		1984 1985	189 230	1992 1993	392 359	2000 2001	318 296	2008 2009	680 658
		1986	232	1993	379	2001	272	2009	780
		1987 1988	240 268	1995 1996	392 418	2003 2004	392 441	2011 YTD	581
1								2022	220/
4.	Num	iber known	to be in illié	gation				3823	33%
5.	Dec	isions on re	quests						11095
	a.	No. grante	ed				1	0182	92%
		(1) By exa					1	0064	
		(2) By Dir	ector (on p	etition)				118	
	b.								
		No. denied	d					913	8%
		(1) By exa						913 878 35	8%
6.	Tota	(1) By exa (2) Reexa	aminer am vacated					878	
6.	a.	(1) By exa (2) Reexa al examiner of Patent ow	aminer am vacated denials (ind	cludes denial				878 35 468	996 48%
	a. b.	(1) By exact (2) Reexact (2) R	aminer am vacated denials (inc ner reques y requested	cludes denial: ter	s reverse	d by Director)	878 35 468 528	996
6.7.	a. b.	(1) By exact (2) Reexact (2) R	aminer am vacated denials (inc ner reques y requested	cludes denial: ter	s reverse)	878 35 468 528	996 48%
	a. b.	(1) By exact (2) Reexact (2) R	aminer am vacated denials (inc ner reques y requested ination pen-	cludes denial: ter	s reverse	d by Director)	878 35 468 528 e)	996 48%

Of the requests received in FY 2011, 6 requests have not yet been accorded a filing date, and preprocessing of 33 requests was terminated for failure to comply with the requirements of 37 CFR 1.510. See Clarification of Filing Date Requirements for *Ex Parte* and *Inter Partes* Reexamination Proceedings, Final Rule, 71 Fed. Reg. 44219 (August 4, 2006).

8. Reexam certificate analysis

			Owner Requester	3 rd Part <u>y</u> Requester	Comm'r Initiated	<u>Overall</u>
	a. b. c.	All claims confirmed All claims cancelled Claims changes	21% 9% 70%	24% 13% 63%	11% 23% 66%	23% 11% 66%
9.	Tota	l ex parte reexamination ce	rtificates issued	d (1981 – presei	nt)	8375
	a. b. c.	Certificates with all claims Certificates with all claims Certificates with claims ch	cancelled		1913 960 5502	23% 11% 66%
10.	Ree	kam claim analysis – reques	ster is patent o	wner or 3 rd party	or Commissio	ner initiated
	a.	Certificates – PATENT OV	VNER REQUE	STER		3026
		(1) All claims confirmed(2) All claims cancelled(3) Claim changes			646 264 2116	21% 9% 70%
	b.	Certificates – 3 rd PARTY F	REQUESTER			5192
		(1) All claims confirmed(2) All claims cancelled(3) Claim changes			1249 660 3283	24% 13% 63%
	C.	Certificates – COMMISSIO	ONER INITIATE	ED REEXAM		157
		(1) All claims confirmed(2) All claims cancelled(3) Claim changes			18 36 103	11% 23% 66%

(b) Statistical data on the number of filed protests for the years 1996-2011

FY	Description	Entries
2011	Protest - 3rd Party (before publication or with applicant's consent)	4
2010	Protest - 3rd Party (before publication or with applicant's consent)	6
2009	Protest - 3rd Party (before publication or with applicant's consent)	13
2008	Protest - 3rd Party (before publication or with applicant's consent)	5
2007	Protest - 3rd Party (before publication or with applicant's consent)	7

FY	Description	Entries
2006	Protest - 3rd Party (before publication or with applicant's consent)	6
2005	Protest - 3rd Party (before publication or with applicant's consent)	12
2004	Protest - 3rd Party (before publication or with applicant's consent)	31
2003	Protest - 3rd Party (before publication or with applicant's consent)	5
2001	Protest - 3rd Party (before publication or with applicant's consent)	2
2000	Protest - 3rd Party (before publication or with applicant's consent)	5
1999	Protest - 3rd Party (before publication or with applicant's consent)	7
1998	Protest - 3rd Party (before publication or with applicant's consent)	4
1997	Protest - 3rd Party (before publication or with applicant's consent)	9
1996	Protest - 3rd Party (before publication or with applicant's consent)	11

EUROPEAN PATENT OFFICE (EPO)

Year	2008	2009	2010
No. of oppositions filed against European patents granted	2800	2700	2770
No. of decisions in opposition cases which took effect	1980	2310	2310
Opposition rate: %	5.32%	4.7%	5.2%

Outcome of Opposition cases: 2010

Rejection of oppositions	29%
Revocation of the patent	33%
Maintenance in amended form	38%