FÉDÉRATION INTERNATIONALE DES CONSEILS EN PROPRIÉTÉ INTELLECTUELLE

INTERNATIONAL FEDERATION OF INTELLECTUAL PROPERTY ATTORNEYS

INTERNATIONALE FÖDERATION VON PATENTANWÄLTEN

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IP 5 Patent Offices:
EPO/JPO/KIPO/SIPO/USPTO

via email: ip5@epo.org

European Patent Office (EPO)
Bob-van-Benthem-Platz 1
80469 Munich
Germany

Japan Patent Office (JPO)
3-4-3 Kasumigaseki,
Chiyoda-ku Tokyo 100-8915,
Japan

Korean Intellectual Property Office (KIPO)
Government Complex Daejeon Building 4,
189, Cheongsa-ro, Seo-gu, Daejeon, 302-701
Republic of Korea

State Intellectual Property Office of the
People's Republic of China (SIPO)
No. 6, Xitucheng Lu,
Jimenqiao Haidian District, Beijing City 100088
P.R. China

United States Patent and Trademark Office (USPTO)
Madison Building
600 Dulany Street
Alexandria , VA 22314
United States of America

RE \\ FICPI Feedback on IP5 Reports relating to Patent Harmonisation

Dear Sirs,

In the name of FICPI, Fédération Internationale des Conseils en Propriété Intellectuelle, I respectfully submit the attached comments, which constitute our Federation's contribution to the IP5 Reports relating to Patent Harmonisation.

Yours faithfully,

Roberto Pistolesi
Secretary General

Enc.

FICPI Feedback on IP5 Reports relating to Patent Harmonisation

FICPI, established in 1906, is a Switzerland-based international and non-political association of approximately 5,500 intellectual property lawyers in private practice from over 80 countries and regions, including from each of the countries and regions of the IP5 Offices. FICPI's members represent the full spectrum of clients including individuals, universities and other research entities as well as small, medium, and large companies. FICPI members not only advise inventors in intellectual property matters and secure protection for industrial innovation on their behalf, but advise third parties on existing rights. FICPI supports predictable, balanced, global protection of inventions, the global harmonization of substantive patent law, and the interest of inventors, applicants and third parties, the whole with deference to local laws and national authorities tasked with granting a fair and appropriate scope of.

FICPI, as an organization, is unique in performing the roles set out above. One of its strengths stems from the experience and broad-based wisdom of its varied membership resulting in positions with a necessarily balanced international perspective. As FICPI is largely comprised of patent practitioners representing foreign inventors, corporate entities, universities, and research institutes, FICPI is poised to give the IP5 Offices the perspective of the international patent community.

FICPI recognizes that the present consultation raises issues of significance to the international patent community worldwide with regard to the scope of protection that is provided in the countries and regions of the IP5 Offices, namely with regard to unity of invention, citation of prior art and written description/sufficiency of disclosure.

FICPI has been following with great interest the work of the IP5 Offices, and has on a number of occasions, particularly in its annual meetings with representatives of the individual IP5 Offices, requested more direct involvement with the IP5 Offices. This desire on the part of FICPI was discussed at FICPI's World Congress and Executive Committee meeting held in Cape Town earlier this year leading to the adoption of a resolution which is reproduced below:

"Office Cooperation and User Input

FICPI, the International Federation of Intellectual Property Attorneys, broadly representative of the free profession throughout the world, assembled at its World Congress and Executive Committee held in Cape Town, South Africa, 13 and 18 April 2015, passed the following Resolution:

Noting that FICPI has been for a long time a well-recognized observer in many law-making processes and believes that it has positively contributed to IP treaties, laws and practices over the years,

Further noting that, as an expansion of the Trilateral Cooperation, the major IP Offices in the world have developed mutual cooperation in groups called the IP5, the TM5 and now the ID5,

Observing that the topics addressed by these groups initially covered procedural and

organisational aspects of office practice but are now progressively expanding to include substantive aspects of IP law and practice,

Further observing that an "IP5 Industry" group has been created that mainly represents large industry from the jurisdictions of the IP5 Offices and provides input to the IP5,

Emphasizing that FICPI members are known for representing the whole range of users of the IP system, including individuals, SMEs, universities and large companies, and that, taken individually, the IP offices of these groups have welcomed the input of FICPI as the practitioners' point of view when discussing law and practice issues and contemplated changes,

Further emphasizing that there is no reason that such input would be of lesser value in the framework of the cooperation between these same IP offices,

Urges the IP offices involved in the IP5, TM5 and ID5 groups to ensure a proper balance in the user input they receive by having FICPI systematically involved in their discussions with users."

In the spirit of this resolution, FICPI provides in the attached three annexes comments in relation to the Reports. We would be very happy to answer any questions the IP5 Offices may have in relation to the feedback provided by FICPI.

FICPI would also like to explore further with the IP5 Offices the possibility of more direct involvement in connection with this important work.

Unity of Invention

The subject of unity of invention is topic of considerable interest to FICPI. The International Patents Study Group of FICPI (CET 3) is currently studying this topic, and is in the process of disseminating a questionnaire to all country delegates to obtain information about how unity of invention is assessed in various jurisdictions. The questionnaire is also expected to reveal the extent to which the patent offices of different countries which are members of the PCT apply the PCT test for unity in the examination of national applications.

During a workshop conducted in late 2014, at a FICPI Executive Committee in Barcelona, agreement was reached in favour of the following concepts:

a| affording applicants the ability to file divisional patent applications at any time during the pendency of at least the original (parent) application,
b| urging Patent Offices to allow applicants an effective opportunity to argue against a lack of unity rejection,
c| urging Patent Offices to consider mechanisms to allow applicants to get all claims searched, and
d| continuing to further investigate the differences in approach and possible routes of harmonization, and to create a pool of knowledge which will be helpful for an applicant when seeking advice regarding unity of invention for different regions/countries.

These findings were consistent with a resolution passed by FICPI in 2002 when WIPO's Standing Committee on the Law of Patents (SCP) was seeking input in connection with a draft Substantive Patent Law Treaty. This resolution, which emphasises the need to balance flexibility against convenience for users, is reproduced below:

"Multiple Invention Disclosures and Complex Applications

FICPI, the International Federation of Intellectual Property Attorneys, broadly representative of the free profession of more than 70 countries, assembled at its Executive Committee meeting held in Newport Beach, California from March, 11 to 14, 2002, passed the following Resolution:

Noting the establishment of a Working Group on Multiple Invention Disclosures and Complex Applications by WIPO's Standing Committee on the Law of Patents in connection with a draft Substantive Patent Law Treaty, and in particular noting the Working Group's mandate to consider inter alia unity of invention and special procedures for treating complex applications;

Appreciating the practical difficulties and financial issues faced by patent offices that are associated with the processing of some complex patent applications;

And recognising that the patent system must be convenient to use for all users and, in particular, that patent examiners and interested parties must be able readily to find potentially relevant patents and published patent applications;

> **But also observing** that unduly rigid application of any 'unity of invention' or 'restriction' practice can lead to unnecessary delays and increased costs to applicants;
>
> **Resolves** that any practice for treating multiple invention disclosures or complex applications should offer maximal flexibility for applicants without compromising the convenience of the patent system for all users."

Although FICPI's current consideration of unity of invention requirements is at an early stage, it became evident at the 2014 workshop mentioned above that there was considerable support within FICPI for the adoption by IP Offices of a consistent and predictable approach to the assessment of unity of invention. It was also recognised that the PCT standard for the assessment of unity of invention might provide an avenue towards such an approach.

However, and as recognised in the IP5 Offices' report on unity of invention, the manner in which different patent offices apply the PCT standard for the assessment of unity of invention is not consistent, leading to different results in different offices. This can cause hardship for PCT applicants who sometimes find themselves unable to obtain full protection for their inventions in a single application in a particular jurisdiction when no unity of invention objection was raised during the international phase. There is clearly a need for the development of guidelines to improve the predictability of unity of invention assessment among the various countries and regions who are party to the PCT. Where unity of invention objections are raised, it is important for IP Offices to provide a mechanism for applicants to challenge the objection, and to request that further searches be carried out in respect of any non-unified and unsearched inventions identified in the objection.

It also became evident at the 2014 workshop that the approach to unity of invention applied by the USPTO, often referred to as "restriction" practice has in no insignificant manner contributed to the way claim sets are routinely drafted by US practitioners. This approach to claim drafting, while acceptable to the USPTO, can often give rise to unity of invention objections when those claims are considered by a foreign patent office. This is particularly the case in the EPO, which office has placed a limit on the number of independent claims that can be presented in a particular claim category. If the USPTO was to replace restriction practice with a standard based on the PCT, there would be a need to ensure a sufficient transitional period to allow US practitioners to adapt the manner in which they draft claim sets. This will be particularly important for US practitioners who primarily handle work for local clients who only pursue protection for their inventions in the US.

FICPI will continue its international study of unity of invention objections, and is happy to share the final results of the study with the IP5 Offices.

Citation of Prior Art

FICPI has recently studied in detail the information disclosure requirements imposed by various national and regional patent offices and has formed the view that several offices are imposing an unnecessary burden on applicants to disclose prior art references to those offices. In some cases patent offices are operating in breach of Article 42 PCT.

The results of FICPI's consideration of this topic were summarised in a resolution passed at the World Congress and Executive Committee meeting held in Cape Town in April 2015. This resolution is set out below:

"Information disclosure requirements from Patent Offices

FICPI, the International Federation of Intellectual Property Attorneys, broadly representative of the free profession throughout the world, assembled at its World Congress and Executive Committee held in Cape Town, South Africa, 13 and 18 April 2015, passed the following Resolution:

Noting that for performing their duty of examining patent applications, some Patent Offices have adopted provisions ("disclosure requirements") requiring applicants to provide information on counterpart applications from other Patent Offices.

Further Noting that the initial rationale for such disclosure requirements was to facilitate examination of patent applications by Patent Offices, in view of difficulties in accessing such information,

Observing that Patent Offices have developed facilities to make accessible, or share, information on their respective patent search and examination processes, and that most of the information requested by Patent Offices is now readily available to them through such facilities,

Further observing that such disclosure requirements from Patent Offices thus place an unnecessary and substantial burden on applicants,

Emphasizing that such burden makes the patent system less accessible to its users, in particular to individual inventors, SMEs and Universities,

Further emphasizing that such requirements from Patent Offices generate legal uncertainty for applicants and for third parties, as it may be difficult for an applicant to be certain to have filed all the required information,

Noting on the other hand that a Patent Office, when acting as an Elected Office and requiring such information, actually breaches Article 42 PCT which prohibits any "elected Office receiving the international preliminary examination report" to "require that the applicant furnish copies, or information on the contents, of any papers connected with the examination relating to the same international application in any other elected Office",

> **Urges** legislators and Patent Offices in jurisdictions with information disclosure requirements to recognize and make use of existing facilities for obtaining such information without putting on the applicant the burden to gather and provide the same, and
>
> **Further urges** Patent Offices to strictly observe Article 42 PCT in case of patent applications that have been examined under PCT Chapter II."

The "existing facilities" referred to in FICPIs resolution include the Global Dossier/CCD and the internet more generally. In many cases, there is simply no need to require the applicant to submit or notify items of prior art relevant to an assessment of the patentability of a claimed invention.

Although FICPI did not give specific consideration to the requirement imposed by some Offices to incorporate into a patent specification references and summaries of prior art documents, this also represents an undue burden for applicants and adds unnecessarily to the cost of pursuing patent protection for their inventions before those offices. In this regard most inventions can be described in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art without the need to refer to items of prior art. The items of prior art considered most relevant during the examination of a patent application will in most jurisdictions, and all IP5 Offices, be available for third parties to see on the publicly available electronic file maintained by the patent office and elsewhere.

It is also important to note that in some jurisdictions, such as Australia, it is disadvantageous for an applicant to refer to prior art in the background section of a patent specification. Prior art references referred to in the specification acquire a special status that allows them to be used to attack the validity of a claim without needing to formally assess whether the prior at reference destroys the inventive step of the claimed invention. Accordingly, any system that requires disclosure of prior art in the specification can impact adversely on applicants when they pursue protection for their inventions outside that system.

FICPI has considered the comments provided in the document entitled "Industry IP5 Consensus Proposals to the IP5 Patent Harmonisation Experts Panel" and supports the proposals provided in relation to the citation of prior art, which are generally consistent with the resolution set out above.

Written Description/Sufficiency of Disclosure

The paper on this topic includes a list of terminology used by the IP5 offices to describe requirements relating to the level and clarity of description or disclosure required to describe an invention and support a claim. Although there is a high level of consistency between the IP5 offices in relation to the terminology used, the manner in which these requirements are applied by the IP5 offices is far from consistent.

Since patent applicants utilising the PCT to pursue patent protection internationally are only permitted to file a single specification to meet the requirements of the IP5 offices, and other patent offices around the world, it is particularly important to improve the consistency of approach to the assessment of claim support and written description on the one hand, and sufficiency of disclosure and enablement on the other hand.

FICPI considers it important for these requirements relating to the nature and quality of the disclosure of the invention to be assessed separately from other requirements, such as utility, industrial applicability and non-obviousness or inventive step. Blurring the boundaries between the requirements for specifications and requirements for inventions can lead to uncertainty for applicants, and difficulties for IP attorneys in advising their clients.

One area of concern recently considered by FICPI is the level of disclosure required by some patent offices for pharmaceutical inventions. This work lead to the adoption of a resolution by the Executive Committee of FICPI in Kyoto in 2014. This resolution is reproduced below:

> "Industrial applicability requirement in pharmaceutical patents
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> **FICPI**, the International Federation of Intellectual Property Attorneys, broadly representative of the free profession throughout the world, assembled at its Executive Committee held in Kyoto, Japan, 6-10 April 2014, passed the following Resolution:
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> **Emphasizing** that according to Art. 27 of the TRIPS agreement, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application;
>
> **Observing** that in certain jurisdictions, pharmaceutical patent applications are rejected and/or pharmaceutical patents are found invalid for alleged lack of industrial applicability or utility, because the specification as filed is considered not to contain sufficient experimental data to enable a sound prediction that the compound or class of compounds recited in the claims would provide in humans the effect disclosed in the originally filed application;
>
> **Recognizing** that data from scientifically acceptable in vitro models or animal models, as well as computer-assisted simulations, are frequently predictive that a given effect would be plausibly achieved in humans and are thus normally relied upon as a basis for drafting a patent application as soon as possible;

Further recognizing that, for safety and/or regulatory reasons, it is rare to have in vivo data on humans available when initially filing a pharmaceutical patent application, particularly if it relates to a new chemical entity;

Noting that having to wait for the availability of in vivo data on humans might seriously prejudice the patentability of the invention for lack of novelty and/or inventive step in particular because of the need or risk of publicly disclosing the invention or of possible intervening publications disclosing the same or similar effect;

Firmly believing that the lack of in vivo data on humans in a patent application does not prevent a pharmaceutical invention from being capable of industrial application;

Urges relevant authorities at a regional and/or national level to refrain from requiring the presence of in vivo data on humans in the application when evaluating the patentability of an invention in the pharmaceutical field;

And further urges relevant authorities at a regional and/or national level to accept post-filing experimental data to support, if necessary, the fact that the compound or class of compounds recited in the claims provides in humans the effect disclosed in the application."

FICPI has considered the comments provided in the document entitled "Industry IP5 Consensus Proposals to the IP5 Patent Harmonisation Experts Panel" and supports the suggestion for the PHEP to work with the Industry IP5 associations to study how these requirements are assessed by the IP5 Offices with a view to the development of some guidelines which could be adopted by the IP5 Offices. The document highlights a number of useful areas to be studied. One additional area would be the approach taken by the IP5 Offices regarding cross references to published materials in providing a description of an invention, for example references to publications describing starting materials used in making an invention, or describing processes that can be adapted to make the described invention. However, to ensure that the study takes into account the perspective of all users of the system, including individual inventors, small to medium sized enterprises (SMEs), Universities and research institutes, FICPI would also like to assist in this proposed study.

IMPORTANT NOTE:

The views set forth in this paper have been provisionally approved by the Bureau of FICPI and are subject to final approval by the Executive Committee (ExCo). The content of the paper may therefore change following review by the ExCo.

The International Federation of Intellectual Property Attorneys (FICPI) is the global representative body for intellectual property attorneys in private practice. FICPI's opinions are based on its members' experiences with a great diversity of clients having a wide range of different levels of knowledge, experience and business needs of the IP system.

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The Australian Federation of Intellectual Property Attorneys, FICPI Canada, Association of Danish Intellectual Property Attorneys (ADIPA), Suomen Patenttiasiamiesyhdistys ry, Association de Conseils en Propriété Industrielle (ACPI), Patentanwaltskammer, Collegio Italiano dei Consulenti in Proprietà Industriale, Japanese Association of FICPI, Norske Patentingeniørers Forening (NPF), Associaçao Portuguesa dos Consultores em Propriedade Industria l (ACPI), F.I.C.P.I South Africa, the International Federation of Intellectual Property Attorneys – Swedish Association, Verband Schweizerischer Patent und Markenanwälte (VSP) and the British Association of the International Federation of Intellectual Property Attorneys are members of FICPI.

FICPI has national sections in Argentina, Austria, Belgium, Brazil, Chile, China, Colombia, Czech Republic, Greece, Hungary, India, Ireland, Israel, Malaysia, Mexico, Netherlands, New Zealand, Peru, Russia, Singapore, South Korea, Spain and the United States of America, provisional national sections in Poland, Romania and Turkey, and individual members in a further 41 countries.

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