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Geneva, May 15, 2017

Public Consultation 01/2017: comments and suggestions of the international associations representing the research-based industry.

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), along with Pharmaceutical Research and Manufacturers of America (PhRMA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the Japanese Pharmaceutical Manufacturers Association (JPMA), and INTERPAT appreciate the opportunity to share our perspectives on the ongoing consultation on patent examination draft guidelines related to the area of chemistry.

Our member companies and the many women and men they employ across Brazil and around the world are devoted to inventing, manufacturing, and delivering valuable medicines that enable patients to live longer, healthier, and more productive lives. Based on experience, we know that a well-designed IP system can support the transformation of valuable ideas into successful solutions which help patients on the ground.

Over the past years, Brazil has made significant advances to enhance the environment for investing in innovation, transferring technology, and ensuring practical application of research outcomes to improve wellbeing. In particular, we support efforts that aim at improving the examination of patent applications. Patent processing that is timely and based on clear, high-quality rules supports innovators in their efforts to push the boundaries of science and technology and deliver products that improve lives. We therefore commend INPI's initiative to review the patent examination guidelines in the area of chemistry – the field that is of a key importance to the pharmaceutical industry.

We are pleased to contribute to the public consultation on this topic in a spirit of constructive dialogue and we look forward to continued engagement with the INPI to create a legal environment in which biopharmaceutical innovation can flourish. In our commentary below we suggest a set of amendments to the draft guidelines which, in our view, would result in increased legal certainty and stronger incentives for innovation.

<u>Inventions relating to compounds found in nature</u>

The patent laws of many countries have consistently recognised the concept that the *practical applications of discoveries* are eligible for patent protection.

This concept (i.e. practical applications of discoveries) has been employed for more than a century[1] to help determine the existence of an invention, and has led most jurisdictions to make patents available for claims directed to "artificial" forms of compounds found in nature – provided, of course, that those "artificial" forms have a practical application (which we note can be confirmed by determining whether the claimed subject matter has an industrial application). Moreover, as WTO Member States are obliged under TRIPS to make patents available for "inventions" within the meaning of TRIPS Article 27.1, WTO Members should ensure that *at least* those inventions that represent practical applications of discoveries are patent-eligible.

In light of the above, the draft guidelines should be amended to clarify that **any** explicit or implicit difference in form (e.g. by way of a limitation to an "isolated" compound, or a compound having level of purity above that found in any natural material or organism) will render a claim to an otherwise "natural" compound patent eligible. This policy is consistent with that contained in the EU Biotechnology Directive[2] and has driven innovative breakthroughs in fields such as diagnostics and personalized medicines.

Novelty of claims to enantiomers and polymorphs

In terms of novelty of a claim, a useful guidance is provided in the 2008 WTO dispute DS27. The Panel Report explained that the ordinary meaning of the word "*new*" (e.g. as defined in the Shorter Oxford English Dictionary) "*suggests something that is "[n]ot existing before; now made or existing for the first time ... Different from a thing previously existing, known, etc.*".

Thus, within the meaning of TRIPS Article 27.1, an invention is "*new*" if it is different in any way from what is described (explicitly or implicitly) in the prior art. In this respect, the draft guidelines can better reflect this interpretation if they specify that claims to enantiomers or crystalline forms will be regarded as novel if they differ in any way from substances and compositions disclosed in the prior art.

That is, whilst novelty can only be asserted if such claims do not encompass known materials, it must be acknowledged where any explicit or implicit limitations of a claim means that it does not encompass any such known materials.

Sufficiency of disclosure for medical use claims

The disclosure standard articulated in TRIPS Article 29.1 merely requires a patent specification to describe the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

It is certainly true that *in vivo* data are useful for confirming that compounds from a Markush grouping indeed elicit the treatment effect(s) specified in a medical use claim. However,

[1] See, for example, UK High Court: *Reynolds v Herbert Smith* ((1903) RPC 123).

[2] Directive 98/44/EC on the legal protection of biotechnological inventions, Article 3(2)

TRIPS does not require the effects of an invention to be *demonstrated* in a patent application, but merely *rendered reproducible* by following the teaching of the application.

We therefore propose that the draft guidelines are amended to: a) remove the blanket requirement for the provision of *in vivo* data for new medical uses; and b) substitute it with a requirement for a case-by-case assessment of whether the application describes the invention in a manner sufficiently clear and complete for it to be carried out by persons skilled in the art.

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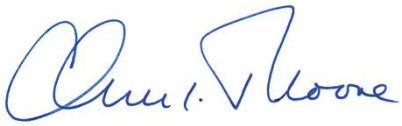
We view the INPI's draft guidelines as a positive step forward to bolster Brazil's patent examination framework. We believe that the suggestions made above – based on good practices and in line with the TRIPS Agreement – will lead to more legal certainty, clarity, and incentives for innovators. Our members are available to support the INPI in assessing what modifications to the patent examination could best support realization of Brazil's policy goals, in keeping with global treaty commitments.

Sincerely,

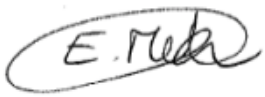
Thomas B. Cueni

Director General, IFPMA



Chris Moore

Deputy Vice President, International, PhRMA



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MINISTÉRIO DA INDÚSTRIA, COMÉRCIO EXTERIOR E SERVIÇOS

INSTITUTO NACIONAL DA PROPRIEDADE INDUSTRIAL

Consulta Pública

Nº 01/ 2017

Formulário de Comentários e Sugestões

Nome: Federação Internacional de Fabricantes e Associações de Produtos Farmacêuticos (IFPMA), Federação Europeia de Indústrias e Associações Farmacêuticas (EFPIA), a Associação de Pesquisadores e Fabricantes Farmacêuticos dos EUA (PhRMA), a Associação Japonesa de Fabricantes Farmacêuticos (JPMA), a INTERPAT

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- ☐ Agente
- ☐ Usuário
- ✓ Representante de órgão de classe ou associação
- ☐ Representante de instituição governamental
- ☐ Representante de órgãos de defesa do consumidor
- ☐ Outros, especificar: _____

Consulta Pública sobre as Diretrizes de Exame de Pedidos de Patente

"Aspectos Relacionados ao Exame de Pedidos de Patente da Área da Química"

Item da Minuta	Proposta de Alteração	Justificativa
2.7	Delete: "Chemical compounds found in nature are not considered inventions, in accordance with the provisions of art. 10 (IX) of the IPL".	This concept (i.e. practical applications of discoveries) has been employed for more than a century (see, UK High Court: Reynolds v. Herbery Smith (1903)) to help determine the existence of an invention, and has led most jurisdictions to make patents available for claims directed to "artificial" forms of compounds

	Replace with: "Claims directed to chemical compounds found in nature are not considered inventions if their scope encompasses a natural material or organism that contains the compound(s) in question. However, such chemical compounds are considered inventions if explicit and/or implicit limitations in the claim(s) to those compounds distinguish the claimed subject matter from the natural material(s) or organism(s) in which the compounds are found".	found in nature – provided, of course, that those "artificial" forms have a practical application (which we note can be confirmed by determining whether the claimed subject matter has an industrial application). Moreover, as WTO Member States are obliged under TRIPS to make patents available for "inventions" within the meaning of TRIPS Article 27.1, WTO Members should ensure that *at least* those inventions that represent practical applications of discoveries are patent-eligible. In light of the above, the draft guidelines should be amended to clarify that **any** explicit or implicit difference in form (e.g. by way of a limitation to an "isolated" compound, or a compound having level of purity above that found in any natural material or organism) will render a claim to an otherwise "natural" compound patent eligible. This policy is consistent with that contained in the EU Biotechnology Directive and has driven innovative breakthroughs in fields such as diagnostics and personalized medicines.
3.3	Delete: "The stereoisomers will be considered new if the state of the art does not describe the enantiomer/atropisomer/diastereomer claimed. Novelty will also be attributed in cases where enantiomers/atropisomers/diastereomers isolated in nature have been described in the state of the art, the antipode to which are now claimed. However, since the state of the art has disclosed the compound in racemic form, the pure enantiomeric or atropisomeric compounds themselves are not considered novel, as the stereoisomeric mixture already has both stereoisomers. It is emphasized that, while the state of the art does not specify the absolute configuration of the chiral centers of the compounds	Under the TRIPS Agreement, claimed subject matter is novel if it differs in any respect from the disclosures of the prior art. To ensure compliance with TRIPS it is therefore essential to highlight that **any** difference over the disclosures of the art (whether due to an explicit or an implicit claim limitation) must lead to the conclusion that the claimed subject matter is novel.

	described, it is assumed that the distribution of the enantiomers occurs equally, or that it is a racemic mixture.". Replace with: "Claims directed to particular stereoisomeric forms (enantiomers/atropisomers/diastereomers) will be not be considered novel if their scope encompasses a known material (e.g. the racemic form) comprising the stereoisomeric form(s) in question. However, novelty will be attributed to claims that contain explicit and/or implicit limitations that distinguish the claimed subject matter from all known material(s) comprising the stereoisomeric form(s) in question. Where the state of the art does not specify the absolute configuration of the chiral centers of the compounds described, it will be assumed that the distribution of the enantiomers occurs equally, or that it is a racemic mixture".	
4.3	Delete: "If the state of the art already discloses the claimed crystalline form, even in a mixture with other forms, regardless of its concentration, the crystalline form claimed is not considered new". Replace with: "Claims directed to particular crystalline forms will be not be considered novel if their scope encompasses a known material comprising the crystalline form(s) in question. However, novelty will be attributed to claims that contain explicit and/or implicit limitations that distinguish the claimed subject matter from all known material(s) comprising the crystalline form(s) in question".	Under the TRIPS Agreement, claimed subject matter is novel if it differs in any respect from the disclosures of the prior art. To ensure compliance with TRIPS it is therefore essential to highlight that **any** difference over the disclosures of the art (whether due to an explicit or an implicit claim limitation) must lead to the conclusion that the claimed subject matter is novel.
9.1.3	Delete:	Under TRIPS Article 29.1, a patent application need only to describe the invention in a manner sufficiently clear and complete

	“If the application intends protection for a new medical use of a "Markush formula", only the use of compounds that have been effectively demonstrated “in vivo” will be considered sufficiently described”. Replace with: “If the application intends protection for a new medical use of a "Markush formula", careful consideration must be given to whether the application describes the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art across the full claim scope. This will be assessed on a case-by-case basis, considering factors such as data supplied by the applicant (e.g. from “in vivo” experiments) and the predictability of the treatment / diagnostic effect from the disclosures of the application, taking into account the common general knowledge of those skilled in the art”.	for it to be carried out by a person skilled in the art. Thus, to ensure compliance with TRIPS, assessments of sufficiency of disclosure must focus **only** upon the issue of reproducibility of the invention across the full scope of the claims. While *in vivo* data are useful for confirming that compounds from a Markush group indeed elicit the treatment effect(s) specified in a medical use claim, a blanket requirement for the provision of such data, without first considering whether the invention is reproducible in the absence of such data, would contravene obligations under TRIPS Article 29.1.

Este formulário deve ser encaminhado ao INPI para o endereço eletrônico: saesp@inpi.gov.br ou diretamente a uma das recepções do INPI.