

**2014 PROCEDURE FOR SUBJECT MATTER ELIGIBILITY ANALYSIS OF
CLAIMS RECITING OR INVOLVING LAWS OF NATURE/NATURAL
PRINCIPLES, NATURAL PHENOMENA, AND/OR NATURAL PRODUCTS**

COMMENTS OF PROFESSOR PAUL COLE AND DR TIMOTHY ROBERTS

1. The writers are two experienced British Chartered Patent Attorneys (having a combined total of 90 years practice post-qualification), who are deeply concerned by the radical change in the principles applied by the USPTO in determining patent-eligibility of claimed subject-matter. One of us (Professor Cole) has already made a submission about this matter (dated June 15, 2014) but now wishes to add to this.
2. We have studied the Guidance, the slides submitted with the presentations at the May 9 forum and the comments made available on the USPTO website up to July 22, 2014. We also contributed to the submission filed by the Chartered Institute of Patent Attorneys dated July 30, 2014. We fully support that submission, but feel it has missed one vital point. **The new Guidance breaches TRIPs.**
3. It is undeniable that technical advance, over the centuries, has vastly improved everyday life in developed countries throughout the world. Increasingly the benefits of technology created in developed countries spread worldwide, reducing poverty and improving life for all. Whatever can properly be done to promote this, must be of advantage to all.
4. Most in developed countries agree that strong, predictable and as far as possible uniform laws for the protection of intellectual property (IP) are vital to promote investment in and development of new technology. Successive US governments have acted in this belief to improve IP laws world-wide. A particular success of US policy has been the adoption of minimum standards of IP protection as a condition for membership of the World Trade Organisation. This is the TRIPs agreement. The TRIPs agreement has been a powerful incentive to many countries to improve their IP laws.
5. It is accordingly a matter of deep concern that the new Guidance appears to contravene the TRIPs Agreement. This is explained below. This can only weaken the effect of the Agreement, encouraging other countries to interpret it restrictively, or even to ignore it. This will be extremely damaging, not just to United States interests, but for investment in research and development throughout the world. Opportunities to make life better will be delayed or lost.
6. We believe that the Guidance does not accord with TRIPs. Any administrative or judicial interpretation of the provisions of any statute,

including 35 USC §101, which places the US in a position where it does not meet the obligations of an international agreement by which it is bound is *prima facie* incorrect and requires reconsideration. It is submitted that the present guidance and e.g. the recent Federal Circuit opinion in *In re Roslin Institute* may be strongly argued to fall into that category.

7. These considerations seem particularly compelling in relation to the Supreme Court opinions mainly relied on for the extended interpretation applied in the Guidance. Those opinions include *Hartranft v. Wiegmann*, 121 U. S. 609, 615, 7 S. Ct. 1240, 30 L. Ed. 1012 (1887), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) and *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Those opinions were well known to and understood by the US Government, the USPTO and US patent attorneys at the time when the TRIPs Agreement was negotiated. The US Government would not have negotiated that Agreement if there was at the time any reasonable ground for belief that US domestic law was inconsistent with the terms being negotiated. There is no basis in law or in logic for assuming that the rulings in those long-established opinions have changed between the time when the TRIPs Agreement was negotiated and now.

7. In negotiating TRIPs, care was taken to ensure that it was consistent with US domestic law. Thus, Article 27 of the TRIPs Agreement is to be read with note 5:

“For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively”

This note plainly links the provisions of the TRIPs Agreement with the language used in US domestic law. In particular, it links industrial applicability, i.e. eligibility, with new utility. We submit that this link reinforces the argument set out above that a difference created by the hand of man and accompanied by further utility should suffice under 35 USC §101.

8. Article 27.1 of TRIPs entitled “Patentable Subject Matter”, we argue, provides a complete code for patent-eligibility which WTO member countries including the US are required to respect. It reads:

“1. Subject to the provisions of paragraphs 2 and 3, *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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of

invention, the *field of technology* and whether products are imported or locally produced.” (emphasis added).

9. Exclusions are covered by Articles 27.2 and 27.3. They include the protection of *ordre public* or morality, protection of human or plant life or health and avoidance of serious prejudice to the environment. They also include diagnostic, therapeutic and surgical methods for the treatment of humans or animals and essentially biological processes for the production of plants and animals. No other exclusions are provided for in that Article. In particular there is no provision for the exclusion of natural products or processes involving natural products or 'laws of nature'.

10. The scope of Article 27 is demonstrated by EU Directive 98/44/EC on the legal protection of biotechnological inventions. This was drafted *inter alia* to be compliant with the TRIPs Agreement to which it makes no less than five specific references. Article 1 of the Directive requires that member states shall protect biotechnological inventions under national patent law and is without prejudice to the implicitly over-riding obligations under the TRIPs Agreement. Article 3.3 provides that biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention *even if it previously occurred in nature*. Article 5.2 provides that an element isolated from the human body or otherwise produced by means of a technical process, *including the sequence or partial sequence of a gene*, may constitute a patentable invention, *even if the structure of that element is identical to that of a natural element*. That is subject to the provisions of Article 5.3 that the industrial application of a sequence or a partial sequence of a gene (i.e. its utility) must be disclosed in the patent application. We submit that the Directive accurately reflects the requirements of the TRIPS agreement, and that national law providing any lesser eligibility falls short of compliance with that Agreement.

11. It follows that the ruling of Justice Thomas in *Myriad* is consistent with the TRIPs Agreement *only* on the narrow interpretation identified by Professor Cole, i.e. that mere isolation of a DNA sequence unaccompanied by new, improved or extended utility does not give rise to eligibility. Any broader interpretation of the ruling e.g. to exclude natural products selected or isolated by the hand of man and possessing new or improved utility would be inconsistent with the express provisions of the Agreement. It will be recollected that Justice Ginsburg during oral argument in *Myriad* was concerned that the US was at risk of adopting a rule quite different from that of other industrialised nations and would be placing itself in an isolated position. Only the suggested interpretation would avoid those concerns, and it is submitted that the Court had these considerations in mind when it handed down its limited and cautious opinion in *Myriad*.

12. There is no basis anywhere in Article 27 for “judicial exceptions” falling outside the language of the TRIPs Agreement. To interpret the Supreme Court's decisions as requiring 'something extra' to distinguish patentable processes from unpatentable 'judicial exceptions' may also be outside the provisions of the TRIPs agreement unless the 'something extra' is new or improved utility, novelty or inventiveness. The exclusion of newly invented or discovered chemical entities or compositions of matter that comply with Article 27.1 note 5 insofar as they exhibit new, improved or extended utility cannot be reconciled with the provisions of Article 27.

13. Article 27.3 specifically provides that microorganisms and microbiological processes shall be patent-eligible. Any prohibition by the USPTO or the US courts on the grant of patents for newly isolated strains of bacteria or other microorganisms having new utility amounts to discrimination as to field of technology contrary to Articles 27.1 and 27.3 of the TRIPs Agreement. Example D of the guidance and the recent Federal Circuit opinion in *In re Roslin Institute* place the US outside the scope of that Article because they purport to exclude naturally occurring microorganisms from eligibility. Example D identifies naturally occurring bacterial strains as falling within judicial exceptions and hence ineligible under §101. The same position is taken by the Federal Circuit in *Roslin*:

“Even before the Supreme Court’s recent decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013), the Court’s opinions in *Chakerabarty* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), made clear that naturally occurring organisms are not patentable.”

14. For the reasons explained below, we dispute the proposition that any of the three cited cases resulted in the holding attributed to them even under US domestic law. As *Chakerabarty* made clear, patents for naturally occurring organisms were granted routinely by the USPTO - at least since 1873 when Louis Pasteur obtained US Patent 141072 directed to: “Yeast, free from organic germs of disease, as an article of manufacture” - and continued to grant such patents at least up to 1970. The EPO routinely grants patents for strains of naturally occurring bacteria. So should the USPTO.

15. As is argued in more detail in CIPA's submission of July 30, respect for the Supreme Court's decisions means accepting the results in the cases before them. It does not require extending the reasoning adopted to other very different fact situations.

16. *Recommendation*

In common with CIPA and many others who have commented, we urge

the USPTO to reconsider the Guidance and new Rules. We strongly recommend that they be replaced with a regime that :

a) implements the findings of recent Supreme Court cases fully but narrowly, so as not to weaken incentives for biological research and development;

b) is coherent with the US policy of promoting strong and uniform patent laws world-wide;

c) is clearly TRIPs-compliant.

Respectfully submitted, July 31, 2014

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