



## INSTITUT PASTEUR

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**DATE :** June 27, 2014

**TO :** Commissioner for Patents  
United States Patent and Trademarks Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

**FROM :** Nicolas TORNO  
Head of Patents and Inventions

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**SUBJECT :** **Response to Request for Written Comments on Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products**

Dear Deputy Commissioner,

Institut Pasteur appreciates the opportunity to offer comments in response to the Request for Written Comments on Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products (the "Guidance").

### *Introduction and General Remarks*

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Institut Pasteur is a non-profit private foundation dedicated to research and public health in microbiology with activities through a network of Institutes in 25 countries around the world. Institut Pasteur contribution to science has been acknowledged over the years with 10 Nobel Prize awards. Institut Pasteur is also known to provide the community with breakthrough in molecular biology, diagnostics and vaccines. This contribution is shared through publications and thousands of patents with the public and with industry to promote innovation and translation to actual medical improvements. Licensing its patent portfolio is an important part of Institut Pasteur resources to continue fund research.

Since the Supreme Court's decision in *Myriad* case, and its proposed interpretation as explained in USPTO Guidance of March 4, 2014, Institut Pasteur is concerned by the uncertainty of the new rule and method to evaluate patent eligible subject-matters in life science. It is expected that discrepancies will arise from case to case, from one examiner to another.

In particular, Institut Pasteur considers the March 4, 2014 Guidance results in extension beyond the scope of *Myriad* Supreme Court Decision.

Institut Pasteur respectfully submits a proposition for an alternative analytical framework for the patent eligibility of life science inventions, completed with examples of eligible claims.

### ***1/ Structural Changes as Unique Standard as Provided by the Guidance is Contrary to Legal Precedents***

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Bringing together the outcomes of both *Myriad* and *Mayo*, the Guidance introduced a significantly different standard for eligibility under 35 U.S.C. §101 for claims reciting judicial exceptions such as natural products. It implies the necessity of a "marked difference" from what exists in nature, or the addition of "significantly more" to the judicial exception.

According to the procedural steps for patent eligibility examination, the Guidance restricts the required marked difference to **structural** changes. Thus, weighs toward eligibility "a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be (...) markedly different *in structure* from naturally occurring products". The examples provided in the Guidance confirm this structure based analytical framework.

On the other hand, the Guidance gave no consideration to the **function** of claimed subject matter, suggesting that a functional difference would not be enough to make a claim eligible, what has been confirmed by Mr. Tamayo during his May 9 Forum presentation.

It is our view that failing to consider the claimed subject matter as a whole, i.e. Structure and Function, the exclusion of function from examination standards is contradictory with relevant legal precedents.

Indeed, previous Supreme Court decisions (*Funk Bros.* (1948), *Chakrabarty* (1980)) considered functional changes as pertinent criterion to patent eligibility. In these precedents, patent eligibility under 35 U.S.C. §101 was considered for claims directed to collections, compositions or living organisms, in view of the consideration of whether the claimed subject-matter changes or not the function compared to natural products.

*Chakrabarty* enjoined to determine whether a natural product recited in a claim exhibits "markedly different **"characteristics"** from any found in nature. By characteristics, it is meant **both structural and functional features**.

In *Funk Bros.*, the Court held that "the composition was not patent eligible because the patent holder did not *alter the bacteria in any way*". Again, here the technical effect and function of the bacteria was taken into consideration.

Moreover, this focus on structural differences setting aside with no consideration on functional differences is an inaccurate interpretation of *Myriad*.

Relying on both *Chakrabarty* and *Funk Bros.* to examine patent eligibility under 35 U.S.C. §101, the Supreme Court in *Myriad* considered that

"Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes",  
(...)

**"Myriad's claims are concerned primarily by the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule"** (emphasis added).

To the Court, "information" of DNA molecule is determined by its "sequence", which combines *de facto* a functional characteristic (information) with a structural one (sequence of DNA). Clearly, in *Myriad*, the information as function was considered for assessing the difference with nature.

In this case, as neither the functional aspects (information) nor the structural ones (chemical composition) were significantly different between the isolated DNA sequence and its natural counterpart, the Court declared the claimed products ineligible. With this holistic approach of claimed subject matter, *Myriad* is consistent with *Chakrabarty* "markedly different characteristics" requirement, the said characteristics combining in this case functional and structural aspects.

However, this important aspect is not reflected in the Guidance.

**Consequently, it is submitted that Structure and Function cannot be separated in assessing "marked difference" with nature.**

## 2/ Proposals for Reintegrating Function as a Criterion

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In view of the above, we propose to resume assessment of claims for patent eligible subject matter as previously defined in *Funk Bros.* and *Chakrabarty*, as well as in strict application of the *Myriad* decision.

In fact, if a claimed product can be derived from nature, i.e. a fragment such as a peptide or a probe, it may have a function which is not found as such in nature. Even more, such different function cannot be derived from nature without the intervention of man consisting of selecting and isolating such fragments for their different function. It is thus not simply the structure which can be "isolated"; the invention can also rely on isolating a specific function not found as such in nature.

- ❖ Thus, applying both function and structure based criteria, a purified composition reciting a natural product such as "purified amazonic acid" (example B of the Guidance) can be seen as providing improved use compared to the unpurified natural product, which often presents a lower therapeutic efficacy due to impurities. This improved function cannot be found as such

in nature, making the purified composition patent eligible. Then, it is rather a question of 35 U.S.C. §102 and §103.

- ❖ A probe specially manufactured to hybridize at a very specific locus of the genome presents both structural and functional features that do not exist as such in any natural configuration. Probes so qualify as eligible subject matter. Again, it is rather a question of 35 U.S.C. §102 and §103.
- ❖ In the same way, a pair of primers manufactured for its use in PCR can even less be found as such in nature, as it consists in a singular combination of products that has no natural counterpart. It is thus patent eligible too.
- ❖ The same applies for antigenic peptide fragments of proteins. First, such peptides cannot be found as such in nature and secondly, their function, i.e. inhibiting TH1, TH2 or TH3 specific immune response, is a specific and isolated function with specific utility. This specific and isolated function is not found as such in nature.

**Consequently, it is submitted that such claims should be found patent eligible on the basis that they are "markedly different" in Function from any natural product.**

*3/ Auxiliary request for clarifying the scope of claims to provide applicants the possibility of integrating explicit Function as a limiting feature*

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It may be of interest to consider letting the applicants the choice to introduce explicit wherein clause to recite function in product claims. This limitation to claims reciting products deriving from nature would entertain prevention of monopolizing "nature".

To this effect, amendments to MPEP 2111.04 on wherein clause appears necessary as today such wherein clause reciting function, use or purpose are deemed limiting only on a case to case basis.

If such formulation and scope is clarified, then a **claim directed to Product X, wherein X is used in Y** would be eligible under U.S.C. §101 even if the marked difference with nature is mainly due to feature Y when nature does not operate Y. By adding such limiting wherein clause, claim scope is limited by reciting positively a specific function of product X, or its specific use in the treatment of a particular disease Y. Such claim would only cover product X for its specific function or its use in Y and not product X for any use or function.

This approach would be consistent with many claim languages used in different countries, including at the EPO which recognize patentability to claims such as Product X for use in Y. In addition, in EU Directive 98/44/EC of the legal protection of biotechnological inventions, the function of the biological product claimed, including isolated DNA, has to be clearly specified in order to comply with patent eligibility. The sequence of a gene is patent eligible even if its structure is identical to that of a natural element, provided the industrial application of the sequence is disclosed in the patent application (article 5-2 and -3). As a matter of fact, the scope of such product claims is limited to the specific use described in the patent.

Finally, the advantage of this proposed approach regarding the "limiting functional wherein clause" would result in harmonization of patent law and practice worldwide.

### *Conclusion*

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Relying on both structure and function to evaluate patent eligibility under 35 U.S.C. §101 would reconcile the assessment for any products deriving from nature whether DNA, purified chemical products, proteins, peptides, antibodies, etc.

So long as the function is different from what derives from nature, the structural changes become less relevant. As indicated above, the question is then rather on 35 U.S.C. §102 and §103, as well as on the scope of product claims.

We respectfully submit that patents with product claims that may be concerned by the *Myriad* decision should be allowed to enter into a **special reissue proceeding** to allow the patentee to amend the claims by specifying the function it intended to protect initially.

We consider that 35 U.S.C. §101 together with legal precedents provide basis for rejoining structure and function in a one simple analysis step for determining if there is a marked difference with nature.

We greatly appreciate the opportunity that has been given by USPTO to provide our comments and we hope our proposals will contribute to amendments to restore legal security and clarify the situation in the general interest.

Best Regards,

A handwritten signature in blue ink, appearing to read 'Torno', with a vertical line extending upwards from the 'o' and a horizontal line extending to the left from the 'o'.

NICOLAS TORNO