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Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of  
the United States Patent and Trademark Office

Andrew Hirshfeld  
Deputy Commissioner for Patent Examination Policy

The United States Patent and Trademark Office  
Alexandria, VA 22313

**Re: Comments to “2014 Interim Guidance on Patent Subject Matter Eligibility”**

Dear Deputy Under Secretary Lee and Deputy Commissioner Hirshfeld:

Thank you for inviting comments and also holding the USPTO Public Forum on the Interim Guidance on January 21, 2015. I also thank you for having provided me the opportunity to speak at the Forum. I am a partner at Dilworth IP, LLC and chair our firm’s life sciences practice area. Please now consider these written comments on the Interim Guidance submitted on behalf of Dilworth IP:

Background and Top Line Comments

In general, the Interim Guidance represents a step in the right direction for the USPTO to deal with the currently dynamic topic of patent subject matter eligibility under 35 USC §101. The Interim Guidance is an attempt to create an integrated framework to bring uniformity and predictability that is needed to support technology-based industries such as biotechnology and information technology. We appreciate the somewhat stormy and critical past situation, and applaud the PTO’s efforts to seek public comment and indication that the Interim Guidance would respond to that.

At the Public Forum I presented on the following topics related to the Interim Guidance. These written comments expand on my presentation.

1. The necessity for the Guidance and how it is a further step in the right direction by the USPTO.
2. The Nature-Based Products “detour” (Section I.A.3, under Flowchart step 2A), how it may be too complex and difficult to apply, and the need for elimination/simplification of this detour.

3. The concern that the “Significantly more” test (Section I.B.1, Flowchart step 2B) is too complex and the need to focus on patent eligibility under the intended §101 determination, not patentability (e.g., §102, §103, etc) determination.
4. A proposal for the USPTO to provide clearer explanations for the Guidance examples.

These written comments expound upon these topics. In particular these comments expound on the 2<sup>nd</sup> item, relating to the Nature-Based Product detour in step 2 of the Guidance, and suggest a change in the framework to address this problem.

#### Positive Aspects of the Interim Guidance

The Guidance is a further step in the right direction by the USPTO. It is an attempt to provide a uniform framework for analyzing all technologies and more closely reflects Supreme Court decisions (*Mayo/Alice Corp*). Additionally it streamlines the previous Guidance by discarding the 12-factor “Significantly Different” analysis that was highly complex and difficult to apply.

The Examiners are instructed to review the entire application disclosure and to give the claims their “broadest reasonable interpretation” in order to determine whether the “claims as a whole” are “directed to a judicial exception.” This is a very positive step, avoiding the previous issue of analyzing individual claim elements and not as a whole. Also, the examiners are instructed to cite their grounds for rejection, specifically identifying the exception from patent eligibility, and explaining their rationale.

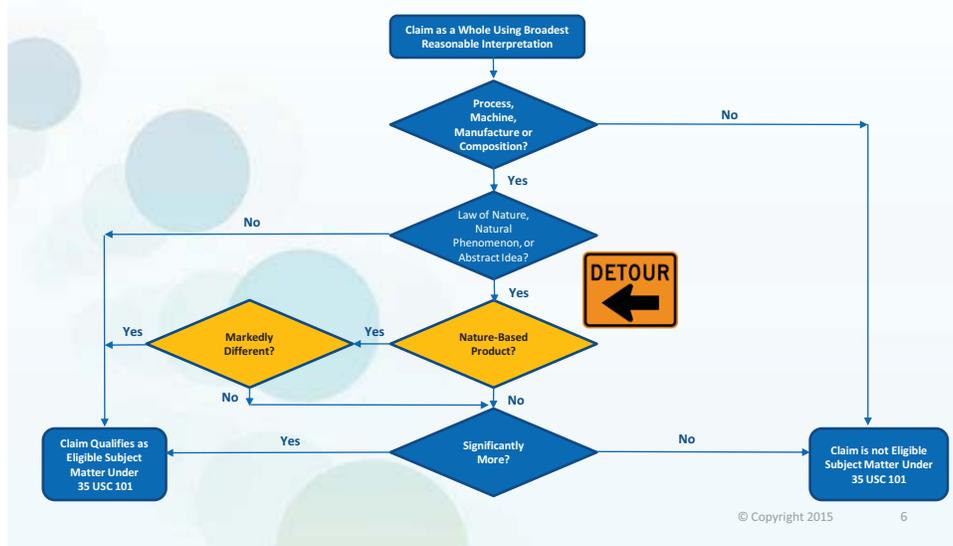
This Interim Guidance is a positive acknowledgment by the USPTO that Patent Subject Matter Eligibility needs to be flexible by considering future revisions, as needed.

#### Suggested Improvements for the Interim Guidance

As pointed out during my presentation on January 21<sup>st</sup>, the Flowchart does not reflect what the Guidance sets forth, because it contains a detour for nature-based products under the Flowchart step 2A (Section I.A.3). See the Flowchart, inserted below from slide 6 of my presentation.

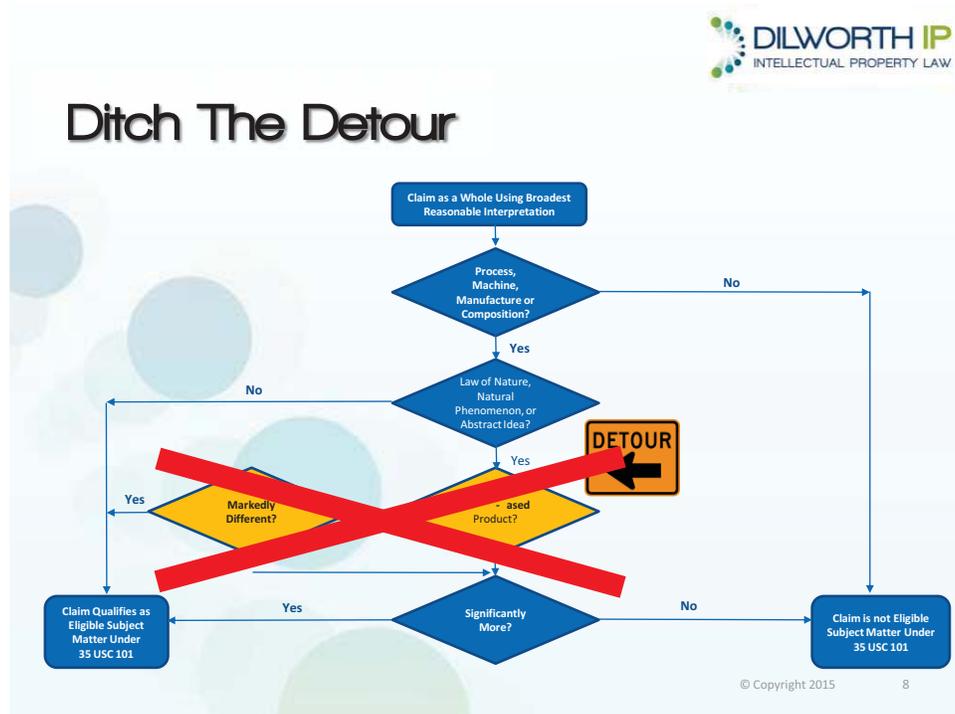


## The Actual Flowchart Has a Detour



It is our view that this detour is confusing, if not unnecessary. Were this subanalysis for nature-based products to remain, it needs to be set forth on the Flowchart as a distinct analysis for particular subject matter, and otherwise integrated into a unified framework for performing the subject matter eligibility analysis.

Furthermore, this detour for nature-based products (the “Markedly Different Test” Section I.A.3. a & b) goes beyond *Mayo/Alice Corp.* and diverges from the consistency being sought across all technology areas. Step 2B of *Mayo/Alice Corp.* does not support this detour and where it is more concisely and simply stated in case law, the Interim Guidance clouds and confuses the step. With the detour comes the risk of getting lost. The detour does not clarify the determination steps. Therefore we recommend the removal of this “Natural-Product detour” to focus the framework on a uniform subject matter eligibility. Respectfully, please “ditch the detour” as suggested on slide 8 from my January 21<sup>st</sup> presentation, as shown below.



Furthermore, removal of this detour will prevent the inappropriate inclusion of §102 (novelty) and §103 (nonobviousness) considerations into the analysis. The purpose of the Guidance is to provide a framework to determine the subject matter *eligibility* of patent claims. This determination should be separate from the subsequent *patentability* determination, i.e. the determinations under §101 (double patenting), §102 (novelty), §103 (nonobviousness), §112 (written description), etc. The potential for misplaced §102 (novelty) and §103 (nonobviousness) determinations are most problematic under this detour provided within Section I.A.3. of the Interim Guidance.

Finally, as a separate point, while the citation of case law in the Interim Guidance is helpful, it is not always clear what the case is cited for. Often cases are cited to both support and argue against a point. The way the citation is being used (either for or against the proposition) needs to be clearly set forth and an explanation provided in the footnote. We respectfully propose that the USPTO review the citations and provide clearer explanations for their use in the Interim Guidance Sample Analyses.

Should you have any questions or wish to discuss these comments and our proposal, please feel free to contact me.

Respectfully submitted,

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