

May 15, 2014

Michelle K. Lee
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 March 4, 2014 “Guidance For Determining Subject Matter
Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural
Phenomena, & Natural Products**

Dear Deputy Under Secretary Lee and Deputy Commissioner Hirshfeld:

Thank you for holding the USPTO Public Forum on May 9, 2014 on the above-captioned Guidance. On behalf of Dilworth IP, LLC, where I chair the biotechnology practice area, I also thank you for having provided me the opportunity to speak at the Forum. Please now consider the following additional comments:

Background

At the Public Forum I presented on the following topics related to the Guidance.

1. The Necessity for the Guidance and how it is a step in the right direction by the USPTO.
2. The Factor Analysis under the Guidance and how it may be too complex and difficult to apply, and the need for simplification.
3. The concern that the Factor Analysis may be misapplied to bring in *patentability* determinations (e.g., §102, §103, etc.), under the intended §101 *patent eligibility* determination.
4. A proposal for the USPTO to provide further Guidance examples

These written comments expound upon the 3rd item, above, relating to the potential misapplication of the §101 patent eligibility determination, and also provide a suggested wording change to both the Question 1 and Question 2 Guidance inquiries to address this problem.

The Patent Eligibility Determination

The purpose of the Guidance is to provide a framework to determine the subject matter *eligibility* of patent claims. Patent eligibility under §101 is a threshold question. 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 probably the most problematic under the Guidance.

The following two examples, both taken from the USPTO's materials on the Guidance, illustrate this issue.

The Pomelo Juice Example

Consider slides 67 to 86 from the USPTO's Training presentation of March 19, 2014. In particular, Claim 1 recites the following:

- Claim 1. A beverage composition comprising:
- a) pomelo juice; and
 - b) a preservative.

The USPTO analyzes this claim for subject matter eligibility under §101 using the flowchart as set forth in the Guidance. In response to Guidance Question 2, "Does the claim recite or involve a judicial exception(s)?", the USPTO says, ". . . yes, because the claim recites a natural product (pomelo is a naturally occurring fruit)." The USPTO then proceeds to analyze the claim under Question 3, "Does the claim as a whole recite something *significantly different* than the judicial exception(s)?" The USPTO performs the Factor Analysis giving the claim its "Broadest Reasonable Interpretation (BRI)" with respect to the preservative, and determines that the balance of factors weigh against patent eligibility.

We respectfully disagree with the USPTO's analysis for two reasons. First, the answer to Question 2 should have been "no" – the eligibility analysis should not have proceeded on to Question 3. Instead, the claim should have then proceeded to a patentability analysis under the other statutory sections. Second, even if the answer to Question 2 should have been "yes", the Factor Analysis under Question 3 should still have led to the conclusion that the claim is patent eligible.

The answer to Question 2, should have been "no", because the "claim as a whole" does not recite a judicial exception. (In our wording change proposal, presented below, I will discuss this "claim as a whole" concept.) A composition of the combination of pomelo juice and a preservative, as recited by the claim, is not naturally occurring. It is recognized that the term "preservative", given its broadest reasonable interpretation, can encompass naturally occurring preservative materials such as tocopherol and ascorbic acid. However, a preserved composition,

of the pomelo juice is itself not naturally occurring. Therefore, the claim should have been deemed patent eligible and allowed to proceed to examination for patentability under §102 (novelty), §103 (nonobviousness), etc.

Even, if for the sake of argument, the answer to Question 2 is “yes”, the Factor Analysis under Question 3 should still have led to a conclusion of patent eligibility under §101. Instead, what has occurred is that the analysis, in comparing each element separately, led to the perverse conclusion that the claim as a whole is patent ineligible.

It is recognized that the claim may not ultimately be patentable when considered under the remaining statutory provisions. However, that determination should not have been short-circuited by an inappropriate §101 eligibility determination.

The Fountain-Style Firework Example

Consider the firework/gunpowder example recited as Example C in the Guidance and discussed in the USPO presentation (slides 52 to 60) of April 16, 2014. The following claim was presented.

Claim: A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) gunpowder, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.

Again, the USPTO analyzed the claim for subject matter eligibility under §101 using the flowchart as set forth in the Guidance. In response to Guidance Question 2, the USPTO answers “yes” because “calcium chloride . . . is a naturally occurring mineral”, and gunpowder, given its broadest reasonable interpretation, “is a mixture of naturally occurring saltpeter, sulfur and charcoal.”

The answer to Question 2, should again have been “no”. The “claim as a whole” does not recite a judicial exception. Even though calcium chloride is naturally occurring and gunpowder (given its broadest reasonable interpretation) is arguably also naturally occurring (although some would vehemently disagree with this characterization), the combination of calcium chloride and gunpowder is not naturally occurring. Furthermore, a fountain-style firework (except perhaps for a volcano) is not naturally occurring, and certainly the cardboard body (unless it is given its broadest reasonable interpretation to encompass cellulosic materials?) and the plastic ignition fuse are not naturally occurring elements of the invention.

It is recognized that the USPTO did find the claim patent eligible under the Question 3 factor analysis, but this further inquiry and analysis should have been unnecessary. The §101 inquiry

should have ended with a “no” to question 2, and the claim should have then proceeded to a patentability determination. What has occurred instead is that by proceeding to Question 3 and its factor analysis, the claims was essentially evaluated for §102 (novelty) and §103 (nonobviousness) considerations rather than just the §101 eligibility determination.

Proposal For Wording Changes to the Guidance Questions

As suggested above, both the Question 1 and Question 2 inquiries should be amended to state the term “claim as a whole”. This change would be consistent with the wording in the Question 3 inquiry. By considering the claim as a whole for the Question 2 analysis, this would eliminate in most instances the contorted analysis whereby each claim element, in isolation, is analyzed as to whether it recites a judicial exception. The more proper inquiry is whether the invention, i.e. whether the claim as a whole, recites or involves the exception.

According to our proposal,

Question 1 would now read: “Is the *claim as a whole* directed to one of the four statutory categories, i.e., a process, machine, manufacture, or composition of matter?”

Question 2 would now read: “Does the *claim as a whole* recite or involve **judicial exceptions(s)**?”

It is our view that by considering the **claim as a whole**, rather than each element separately, as is done by the USPTO in the above pomelo juice and fireworks examples, the answer to Question 2 would have been “no” in each instance, and the claims would then have proceeded to a patentability determination, rather than the potentially misplaced analysis under Question 3. Finally, even though the Question 1 inquiry seems straightforward and is not apparently at issue here, for consistency, Question 1 should also be amended to consider the claim as a whole.

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

Respectfully submitted,



Anthony D. Sabatelli, PhD, JD
Partner

cc: Michael Dilworth, JD
Founding Partner