May 9, 2014

Comments in Response to

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2014–0024]

Notice of Forum on the Guidance For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, and Natural Products

presentation by

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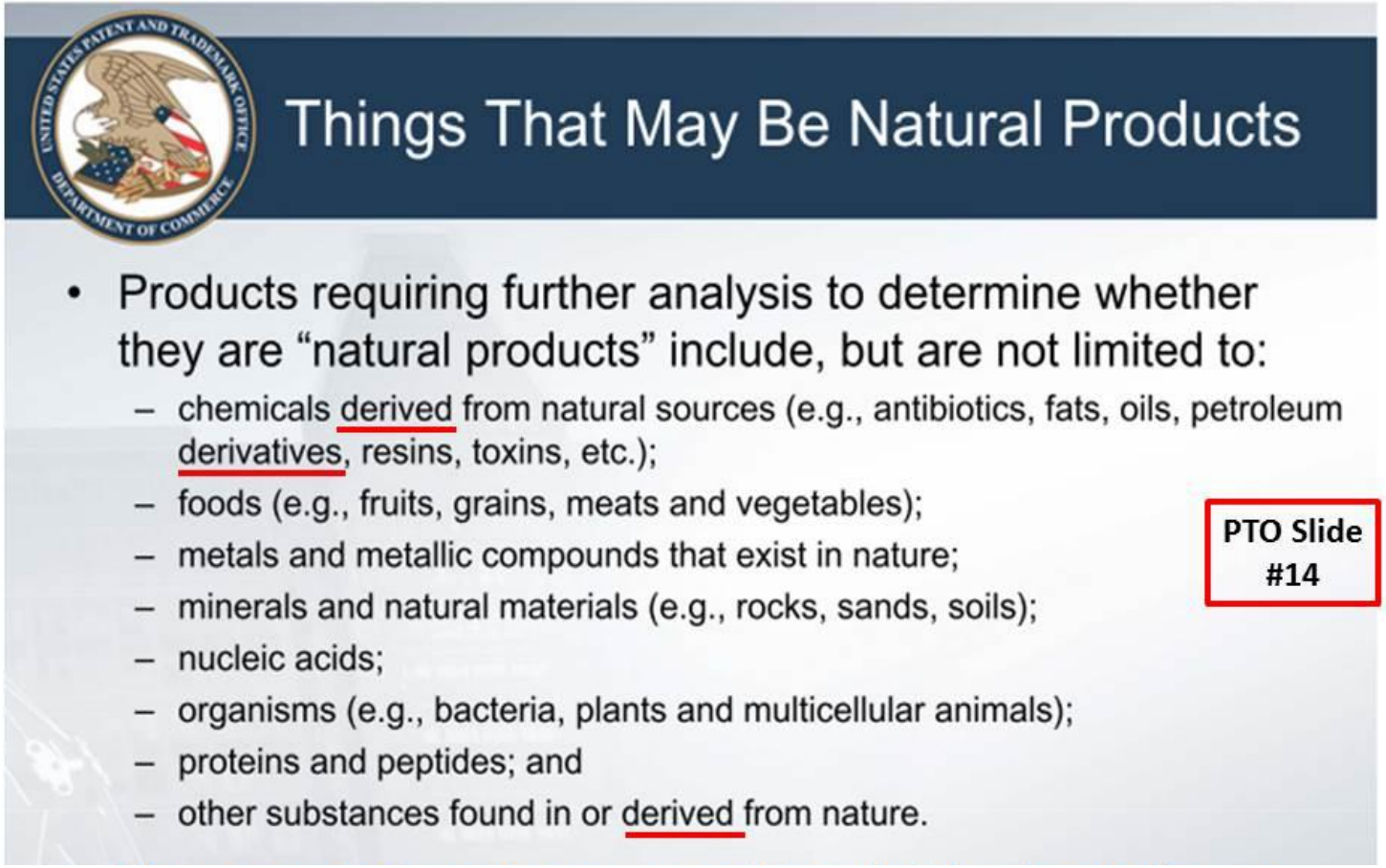
All should appreciate your work on clarifying criteria for Utility Patents.

This presentation addresses part of the 67-slide presentation under

PTO's file name: *myriad-mayo_bcp_20140416*

Here are some observations and questions of concern:



USPTO slide #14 uses the words "derived" and "derivatives" where you see underlined.

What does each word imply?

GV3

Have you better defined these words somewhere?

I trust when you use "derived", you mean that a substance was taken out of the natural source, by some means, so that the substance retains its chemical identity but may now be more isolated or concentrated or appropriate for further utilization.

Such a substance

which has to be in the form of a solid, liquid or gas,
would require PTO, one would guess,
to call it a "natural product",
Yes?

Refreshing our history,
remember Mr. Justice Frankfurter's
concurring opinion in
Funk Brothers Seed Co. v. Kalo Inoculant Co.,
333 U.S. 127, 131 (1948)?

"Everything that happens
may be deemed
'the work of nature,'
and any patentable composite
exemplifies in its properties
'the laws of nature.' " [1]

A more contemporary author has also mentioned "Laws of nature" or, in other words,

"natural laws … are
descriptions of what happens
not prescriptions of what must happen.

Natural laws don't really cause anything, they only describe what regularly happens in nature.

They describe the effects of the four known natural forces –
gravitation, magnetism, and the strong and weak nuclear forces." [2]

“Once you introduce intelligent being into the picture, natural forces can be overpowered……

For example, when a baseball player catches a falling baseball, he is overpowering the force of gravity.

We do the same whenever we fly planes or blast off into space. In such cases, gravity is not changed, it is simply overpowered.” [2]

So, the 2012 court opinion in

Mayo Collaborative Services v. Prometheus Laboratories, Inc.,
566 U.S. __, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012),

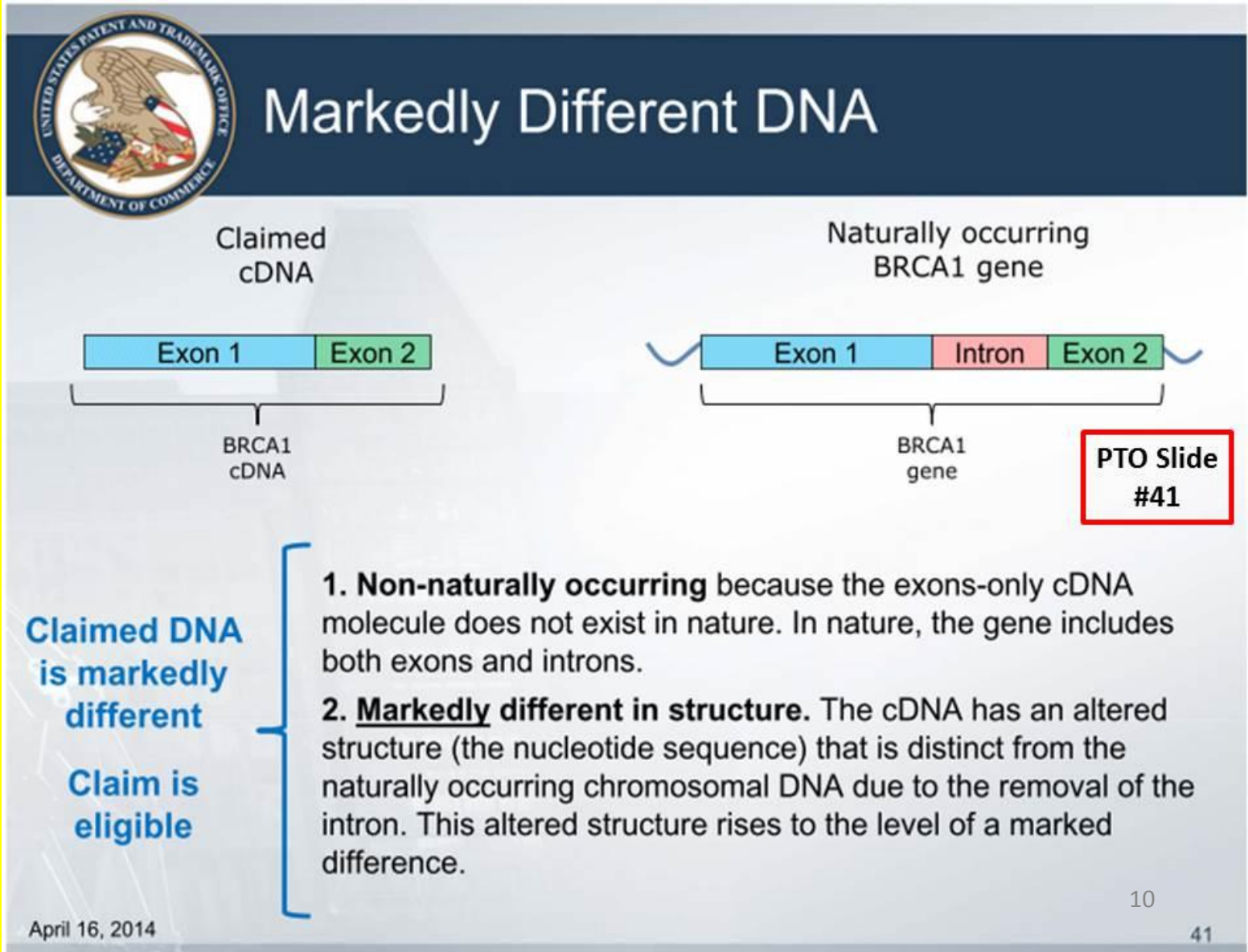
showed us the correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drugs are not patentable. [3]

Then in the 2013 opinion,

Association for Molecular Pathology v. Myriad Genetics, Inc.,
569 U.S. __, 133 S. Ct. 2107, 106 USPQ2d 1972 (2013)

showed us that taking parts of a DNA and putting them back together as cDNA is not a natural product. [4]

USPTO slide #41 is a great description of their patent's "piecemeal" synthesis:



So, all the previous is being given to say this:

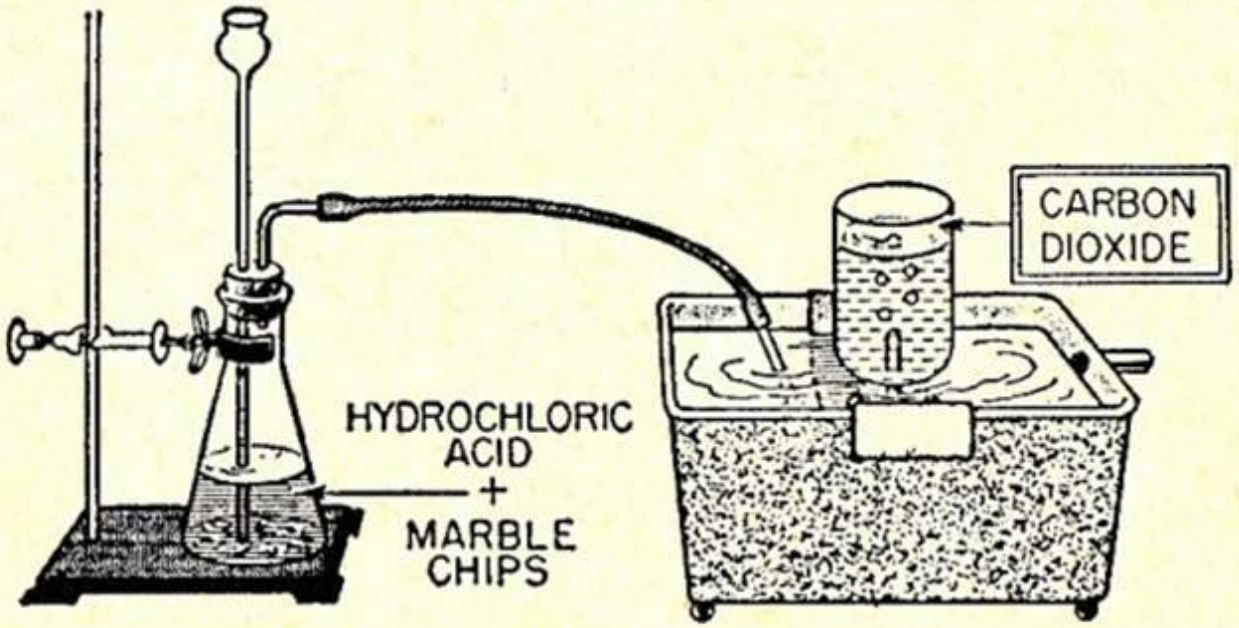
It appears that we are constantly finding new and newer

“descriptions of what’s happening!

Should the definitions and explanations of
"derived" and "derivatives"
need to be better shown through many examples
that would be helpful for
examiners and patent applicants alike?

Here shows a real simple method [5] of chemically "finding" a natural product, Carbon Dioxide:

General Method.—Action of a dilute acid on a carbonate.



$$CaCO_3 + 2HCl \longrightarrow CaCl_2 + H_2O + CO_2\uparrow$$

Many times that is "all" the invention does, is "find".

So, back to USPTO slide #14.

A chemist would be concerned about using "derivatives" blatantly.

He would use derivative to mean the formation of a new chemical that has a different structure than the original chemical (say "Z") which was used initially in a reaction or multi-step process.

So that, every chemical formed downline from chemical "Z", would be called a "derivative".

In our case here, "Z" would be the "natural product“ and NOT a "derivative". Yes?
And how about the other items?

Generation Class	Base or Derivative	Process	A Natural Product per 35 U.S.C.§101	
			Yes?	No?
Natural source	Pine tree	Tree grew from seed or cutting		
1st	Pine oil	Physical extraction		
2nd	Ethoxylated pine oil	Ethoxylation		
3rd	Chlorinated ethoxylated pine oil	Chlorination		

Now, this example chart above outlines the synthesis of two "derivatives" from pine oil. Obviously, the process involved in each step would have to be considered for decision on patent application.

This same example should also be described in English prose when it comes to explanations for patenthood, but a chart is sometimes easier to understand as a complementary tool.

Generation Class	Base or Derivative	Process	A Natural Product per 35 U.S.C.§101	
			Yes?	No?
Natural source	Pine tree	Tree grew from seed or cutting		
1st	Pine oil	Physical extraction		
2nd	Ethoxylated pine oil	Ethoxylation		
3rd	Chlorinated ethoxylated pine oil	Chlorination		

Such a checklist would provide a NO or NoGo starting point for the further elucidation of the actual process involved with natural products.

It may be interesting as USPTO develops more details in this 35 U.S.C.§101 area that more attention may be placed on specific examples (albeit, even hypothetical) that couple diagrams, pictures, graphs, charts and checklists to help better explain the invention.

Footnotes:

[1] Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948)

[2] Norman L. Geisler and Frank Turek in ISBN1-58134-561-5 (2004), p.204

[3] Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. __, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012)

[4] Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. __, 133 S. Ct. 2107, 106 USPQ2d 1972 (2013)

[5] William Lemkin, Graphic Survey of Chemistry, Oxford Book Company (1960), p.470

Thank you for this opportunity to address this USPTO area of activity.

Recompiled: May 2, 2014

(from prelim April 25th notes)

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