USPTO's 101 Eligibility Forum

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Eligibility of "Weighted" and "Combination" Diagnostic Assays

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Patent Laws are Statutory Laws

Exceptions to statutory laws should be construed narrowly

Exceptions to statutory laws should not undermine statutory policy

- The Rehnquist Court's Canons of Statutory Construction by Judge Russell E. Carparelli, Colorado Court of Appeals, Sep. 2005 (citing the Appendix to "Foreword: Law As Equilibrium," William N. Eskridge, Jr., Philip P. Frickey, 108 Harv. L. Rev. 26, Nov. 1994)

To promote the Progress of Science and useful Arts…

Section 101 is broadly written to define eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" whether invented or discovered.

"…Congress plainly contemplated that the patent laws would be given wide scope." *Chakrabarty*

"[Courts] should not read into the patent laws limitations and conditions which the legislature has not expressed." *Chakrabarty*

"It is the role of Congress, not [courts], to broaden or narrow the reach of the patent laws." *Chakrabarty dissent*

New and Unforeseen Inventions

One could start with the wheel…

Sea shells ≠ fruit ≠ a mixture of bacteria ≠ a bacterium having a mixture of plasmids ≠ hybrid seeds ≠ isolated DNA ≠ Dolly ≠ primer pairs

Similarly, product claims ≠ process claims, so

Transmitting signals ≠ updating alarm limits ≠ curing rubber ≠ detecting a vitamin deficiency ≠ hedging bets ≠ optimizing efficacy of 6-thioguanine ≠ screening for a BRCA1 mutation

Otherwise, there would have been no case or controversy for the courts to render these decisions

And, the court in each case interpreted the prior decisions narrowly

Courts narrowly construe judicial exceptions

Even when the subject matter at issue is related

In fact, in *Ambry*, the Federal Circuit narrowly construes the judicial exception expressed by the Supreme Court in *Myriad* and stated that:

"But, nowhere in the opinion did the Court express approval [or disapproval] of the individual claims identified by Judge Bryson, much less of claim 21 in particular. Indeed, no method claim was even before the Supreme Court."

USPTO Guidance and Examples

The USPTO is commended for its diligent efforts in attempting to provide guidance for the benefit of both examiners and stakeholders

Nevertheless, the USPTO should strongly emphasize to Examiners that the Guidance

- Is not law as it cannot account for new and unforeseen inventions; and
- The USPTO Guidance and Examples should be narrowly interpreted and narrowly applied

As an example, and without acquiescing to the USPTO's analyses in the Guidance and Nature-Based Product Examples, I'd like to address "weighted assay" claims

Metabolite's Claim 13 US 4,940,658

"They did not claim that LabCorp's use of the Abbott test infringed the patent's claims describing methods for testing for homocysteine. Instead, respondents relied on a broader claim not limited to those tests, namely, claim 13, the sole claim at issue here."

13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

- assaying a body fluid for an elevated level of total homocysteine; and
- correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

Prometheus' Claim 1 US 6,355,623

"We find that the process claims at issue here do not satisfy these conditions."

"We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them."

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
   - (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
   - (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
   - wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
   - wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

URF's Claims 7 and 8 US 5,753,441 (paraphrased)

"But, nowhere in [*Myriad*] did the Court express approval [or disapproval] of the individual claims … Indeed, no method claim was even before the Supreme Court."

7. A method for screening a subject for an alteration of a BRCA1 gene which comprises
   - comparing the sequence from the subject with the wild-type sequence, wherein a difference between the sequences indicates the alteration
   - wherein the comparing is by hybridizing a BRCA1 gene probe specific to the alteration, and
   - detecting the hybridization product the presence of which indicates the presence of the alteration.

8. A method for screening a subject for an alteration of a BRCA1 gene which comprises
   - comparing the sequence from the subject with a wild-type sequence,
   - wherein a difference between the two sequences indicates the presence of the alteration, and
   - wherein the comparing is by using a set of primers to produce amplified amounts of the sequence from the subject that are then sequenced and compared to the wild-type sequence.

URF's Claim 21 US 5,753,441 (paraphrased)

"Even if claim 21 of the '441 patent were patent eligible—a question about which we express no view—claim 21 is qualitatively different from the method claims at issue here."

21. A method for screening a subject for an alteration of a BRCA1 gene, said alteration is selected from those set forth in Tables 11 and 12, which comprises

- comparing the sequence from the subject with the wild-type sequence, wherein a difference between the sequences indicates the alteration
- wherein the comparing is by hybridizing a BRCA1 gene probe specific to that set forth in Table 11 and 12, and
- detecting the hybridization product the presence of which indicates the presence of the alteration.

Exemplary "Weighted" Assay Claims

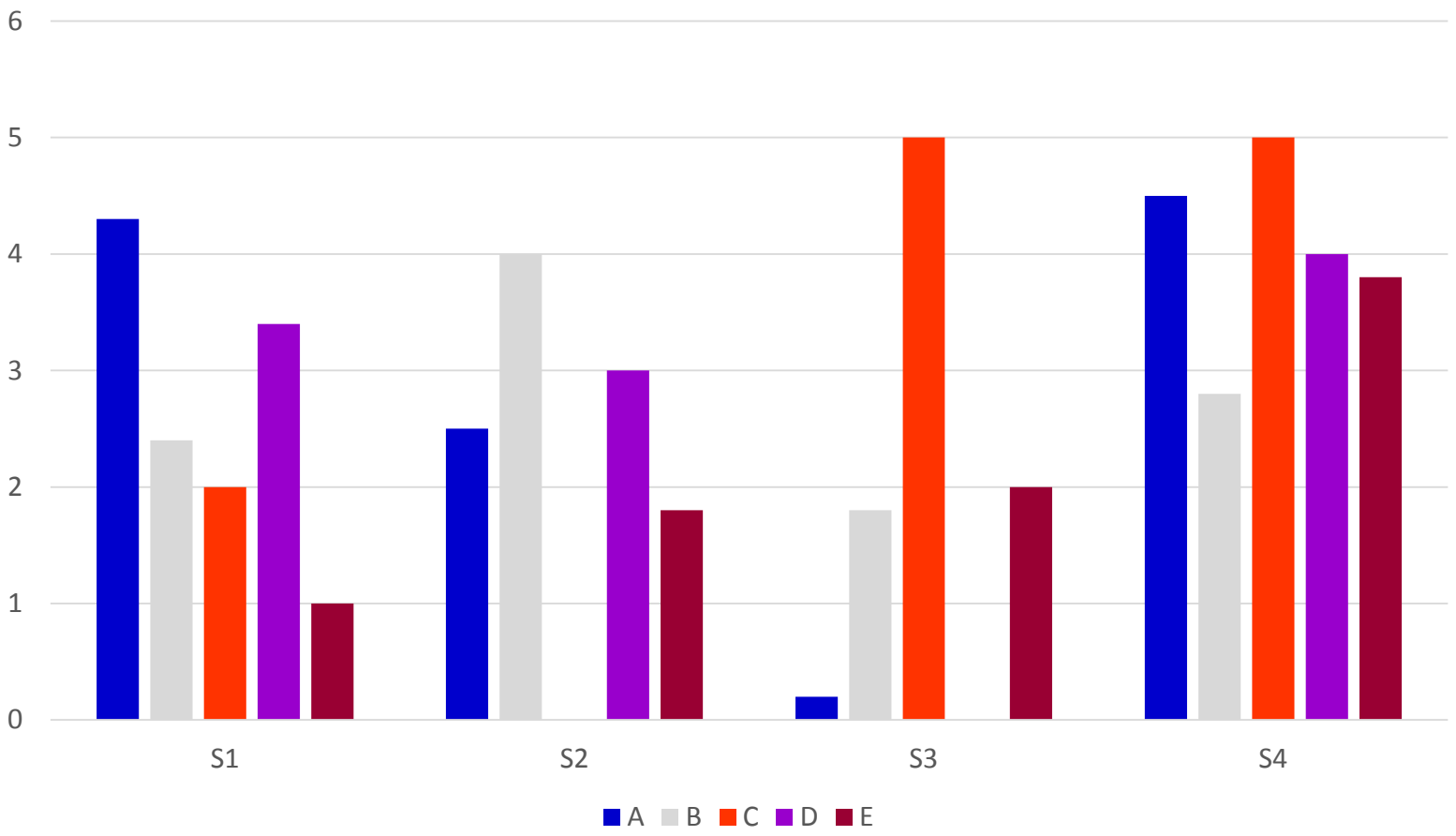
One or more Biomarkers A, B, C, D, and E are found in both healthy and diseased subjects

One healthy/diseased subject may have different amounts compared to another healthy/diseased subject

1. A method of diagnosing a subject as having a Disease which comprises
   - measuring the amounts of at least 3 biomarkers selected from the group consisting of A, B, C, D, and E,
   - assigning a weighted value to each measured amount of each biomarker, multiplying the amounts measured as follows Ax0.5, Bx0.4, Cx0.8, Dx0.2, and Ex0.9,
   - summing the total of the weighted values, and
   - diagnosing the subject as having the disease when the total of the weighted values is above 25.7.

2. A method of diagnosing the likelihood of a subject as having Disease D which comprises
   - measuring the amounts of at least 3 biomarkers selected from the group consisting of A, B, C, D, and E,
   - using Algorithm A, $$P_Z = \frac{e^{\alpha+\beta_1 X_1+\beta_2 X_2+\ldots+\beta_P X_P}}{1+e^{\alpha+\beta_1 X_1+\beta_2 X_2+\ldots+\beta_P X_P}}$$
   - and diagnosing the subject as having N% likelihood of having the Disease where the predicted probability is n and 0<n> and N = n x 100.

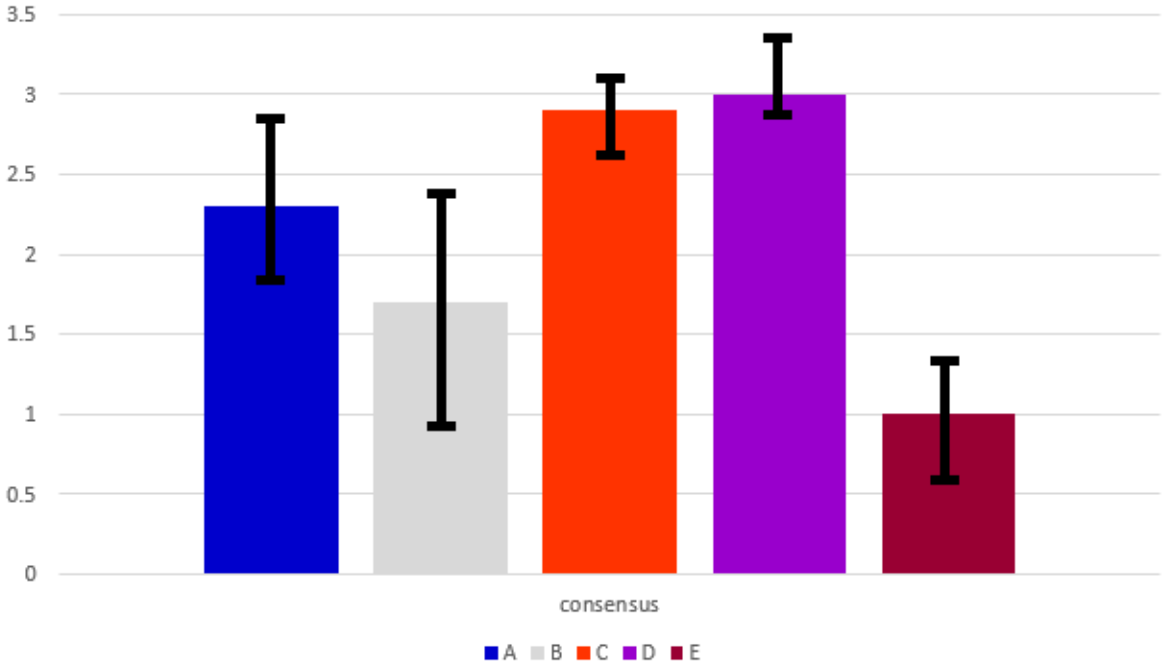
Amounts in Healthy/Diseased



No Consensus Profile

It is possible that there is no consensus profile for the measured amounts of the biomarkers

It is possible there is a consensus profile for the measured amounts of the biomarkers, but such doesn't account for all or other factors



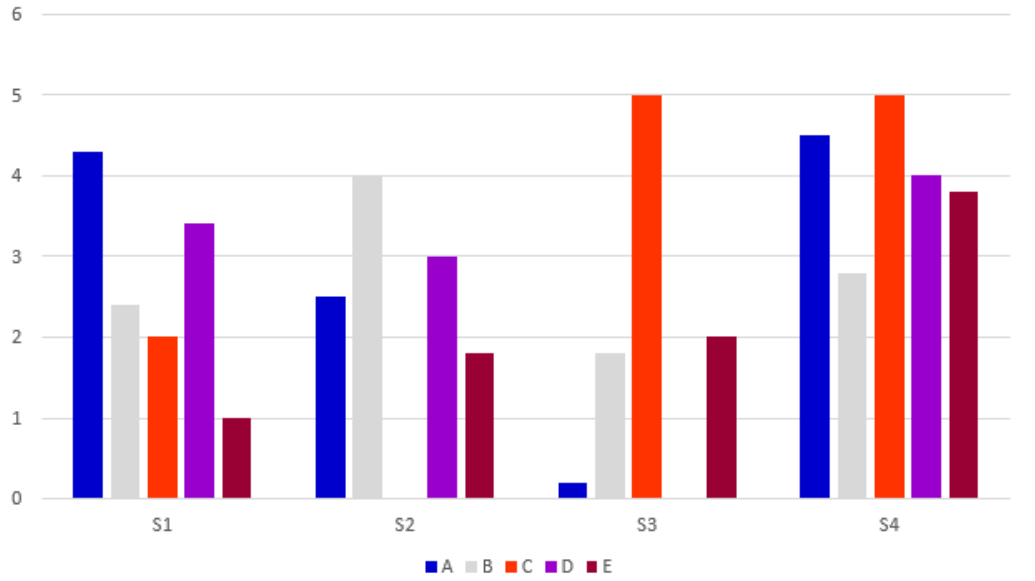
When Judicial Exceptions are properly narrowly construed

"COMBINATION" ASSAY CLAIMS ARE ELIGIBLE

Exemplary "Combination" Assay Claims

1. A method of diagnosing a subject as having a Disease which comprises detecting the presence or absence of Biomarkers A, B, C, D, and E, and diagnosing the subject as having the Disease where at least 3 of the Biomarkers are detected as being present.

Amounts in Healthy/Diseased



A Line in the Sand is Forming…

First, remove the judicial exception and see what's left

INCORRECT

STRIPPING THE CLAIM

Is there an inventive concept in what is left behind?

Just about every assay claim, not just diagnostic claims, will be ineligible using this method

Thus, this approach is incorrect as it undermines the broad statutory policy of 101

CORRECT

CLAIM AS A WHOLE

Is there a nexus between the remaining steps (including any so-called conventional or routine steps) that pins the judicial exception to a practical application?

If yes = eligible, if not ineligible

USPTO should NOT follow the incorrect approach

TO DO SO WILL CAUSE THOSE WHO CAN TO BECOME THOSE WHO DON'T BRING LIFE-SAVING TECHNOLOGIES TO THE AMERICAN PUBLIC

Don’t discourage innovation

While the courts are struggling towards the correct approach which is narrow construction of judicial exceptions to statutory laws

Correctly interpret the recent 101 decisions for what they are…

Narrow judicial exceptions to a broadly written statute that states “any” new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof invention OR discovery.

We have a responsibility to the American public

TO ENSURE THE PROGRESS OF SCIENCE AND USEFUL ARTS

If we fail, we will…

Not likely discover the cure to cancer and other diseases such as Alzheimer's Disease, Down's Syndrome, autoimmune disorders, and the like

Lose our status as an economic world leader and topple from being one of the top ranking leaders in science and technology

And lose even more American jobs to overseas

America failing is not the intent of our Constitution and Congress

WE MUST NARROWLY CONSTRUE THE JUDICIAL EXCEPTIONS UNTIL CONGRESS TAKES ACTION