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Intellectual Property Attorneys

PATENT PROTECTION FOR HIGH TECHNOLOGY

§ 101 Inherency: A Survey of Federal Circuit Decisions

Why Wining the Battle May Include Losing the War

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Prometheus Labs, Inc.

v.

Mayo Collaborative Services

(Fed. Cir. 2009, 2008-1403)

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Prometheus v. Mayo

- There was a pre-*Bilski* District Court decision holding the invention was not patent-eligible under 35 U.S.C. § 101
  - *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), cert. granted, 129 S. Ct. 2735 (June 1, 2009).
- The Federal Circuit held, post *Bilski* that the invention was patent-eligible 35 U.S.C. § 101

- This case was decided only on the transformation leg of the Machine-or-Transformation test of *Bilski*. Thus, any references to the machine leg of the test will be brief.

Posture of the Case

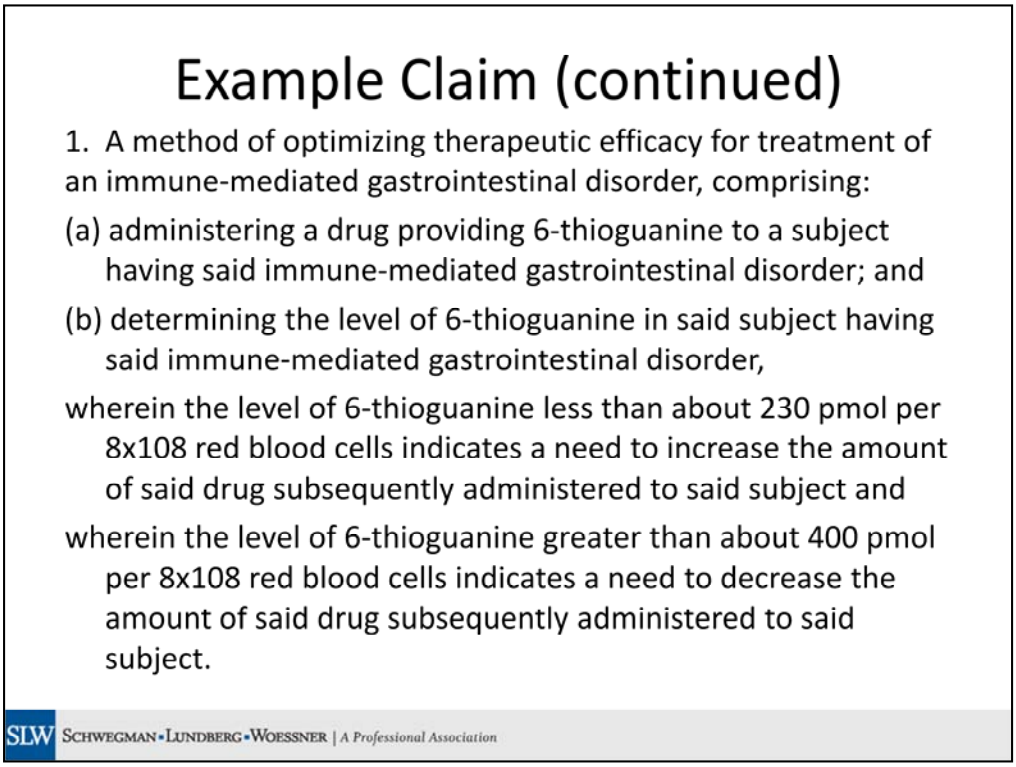
- Appeal from a grant of Summary Judgment by the Southern District of California in favor of Mayo that the 6,355,623 and 6,680,302 patents are invalid as being directed to non-statutory subject matter under 35 U.S.C. § 101.

- Prometheus appealed to the Federal Circuit.

Technology Involved

- Methods of a treatment protocol to calibrate a proper dosage of thiopurine drugs used for treating both gastrointestinal and non-gastrointestinal autoimmune diseases (i.e., inflammatory bowel diseases such as Crohn's disease and ulcerative colitis)

- The proper dosage is important to avoid toxic side effects from over dosing, while maintaining a minimal dosage to ensure the drug's efficacy.



The opinion included claim 1 of the '623 patent as exemplary of both patents at issue.

The determining of the 6-thioguanine level involves a measurement. To perform the measurement, the application disclosed two techniques which involved separating out metabolites from a blood/skin sample (such as high pressure liquid chromatography) and performing the measurement.

Chromatography involves a physical transformation of the sample (i.e., blood) to allow for metabolites to be measured.

District Court Claim Construction

"indicates a need" construed to mean:

> "a warning that an adjustment in dosage may be required"

This construction did not require doctors to adjust the drug dosage if the metabolite level reached the specified levels.

Rather, it means that when the identified metabolites reach the specified level, the doctor is warned or notified that a dosage adjustment may be required, if the doctor believes that is the proper procedure.

Grant of Summary Judgment

Fact that claims framed as treatment methods does not render claims patentable;

The administering and determining steps are data gathering steps for use of the correlations;

The warning step is only a mental step that does not require any change in dosage;

***The correlations are natural phenomena** resulting from a natural body process and the correlation was not invented;*

"Because the claims cover the correlations themselves, it follows that the claims 'wholly pre-empt' the correlations."

Federal Circuit Discussion of the Law

35 U.S.C. § 101

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.

But not solely a fundamental principle (i.e., law of nature, natural phenomenon, abstract idea), although an application thereof is patent-eligible.

35 U.S.C. § 101 in *Prometheus*

"The key issue for patentability, then, ***at least on the present facts***, is whether a claim is drawn to a fundamental principle or an application of a fundamental principle."

Note this statement. At the end of the day, the application of this case may be limited to the specific facts of the case. Nonetheless this is the most important post-Bilski case from the Federal Circuit to date.

Guidance of *Bilski*

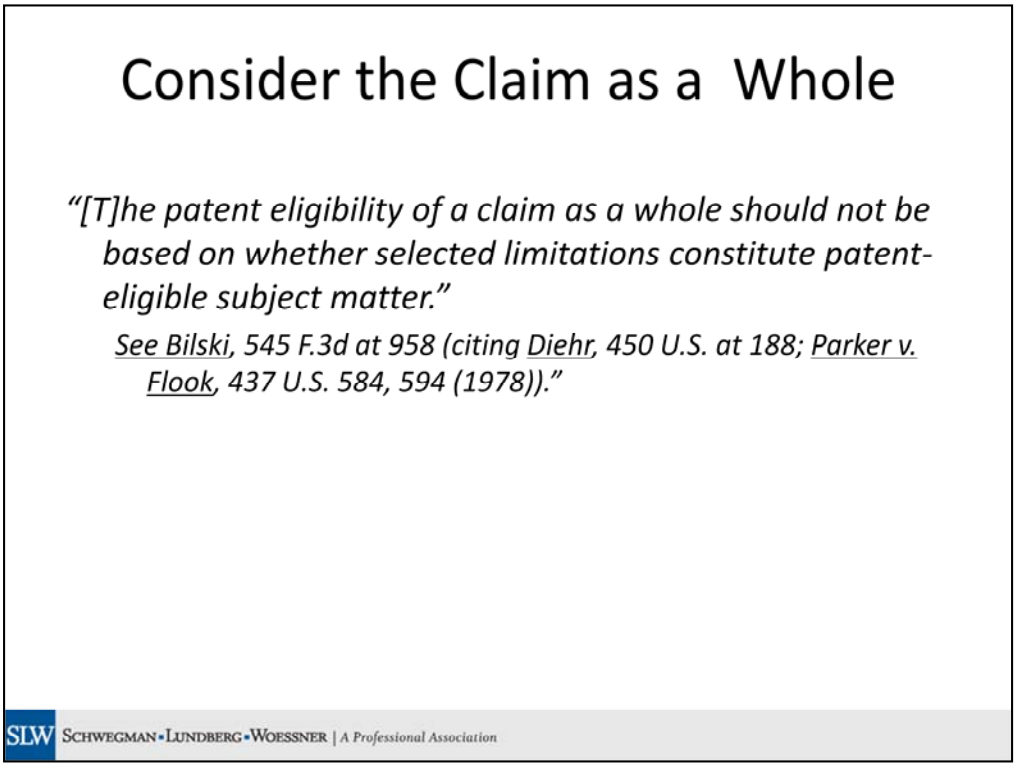
A claimed process is patent-eligible under § 101 if:

(1) it is tied to a particular machine or apparatus, or

(2) it transforms a particular article into a different state or thing.

But the machine or transformation must:

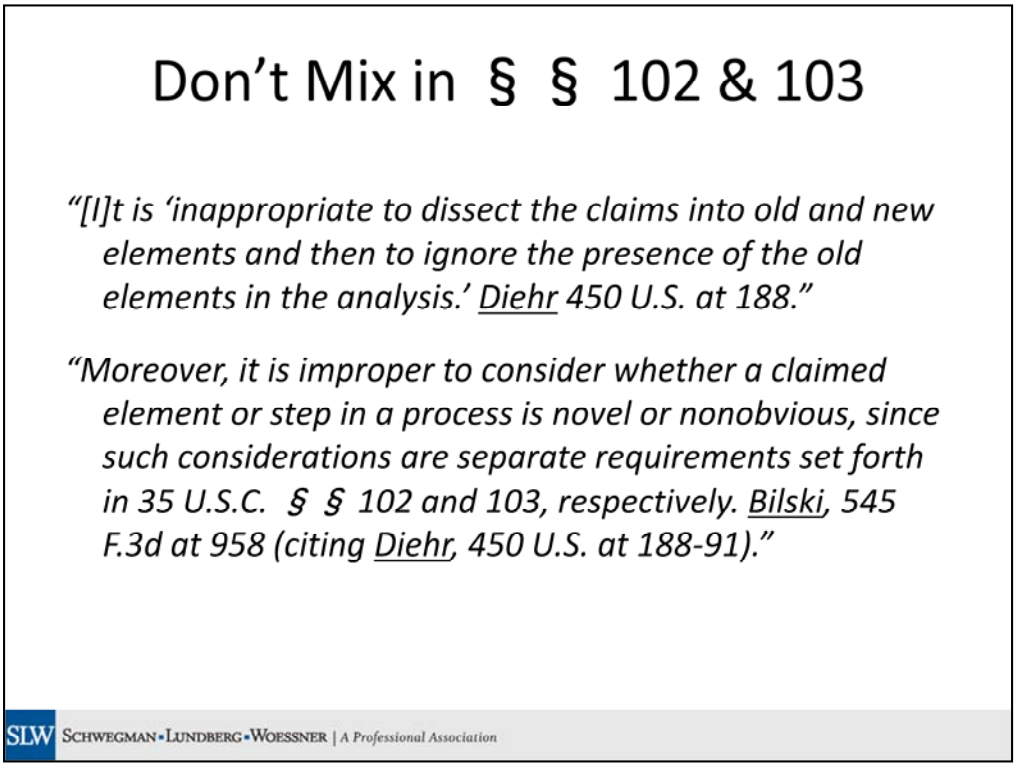
- "impose meaningful limits on the claim's scope"
  - More than plugging in the machine to an electrical outlet;
- "not merely be insignificant extra-solution activity"
  - i.e., the machine or transformation must be central to the purpose of the claim.



Don't look at just individual elements and ignore, or blue-line, elements that do not include a machine or transformation as the machine or transformation may be provided through a combination of elements.

Also, just because one element fails to include a machine or transformation, that does not mean the claim as a whole is not patent eligible.

Thus, if just a single element of a claim includes an acceptable machine or transformation, when viewing the claim as a whole, the claim is patent eligible.



What the Court is stating here is that just because a particular claim element may be in the prior art, that is not a valid consideration under 35 U.S.C. § 101. Thus, even if a claim element that provides the only machine or transformation in the claim is in the prior art, so long as the element provides a machine or transformation that imposes a meaningful limit on the claim and is more than mere insignificant extra-solution activity, that particular element brings the claim within the realm of patent eligible subject matter. Again, considering the claim as a whole.

Thus, Under § 101 …

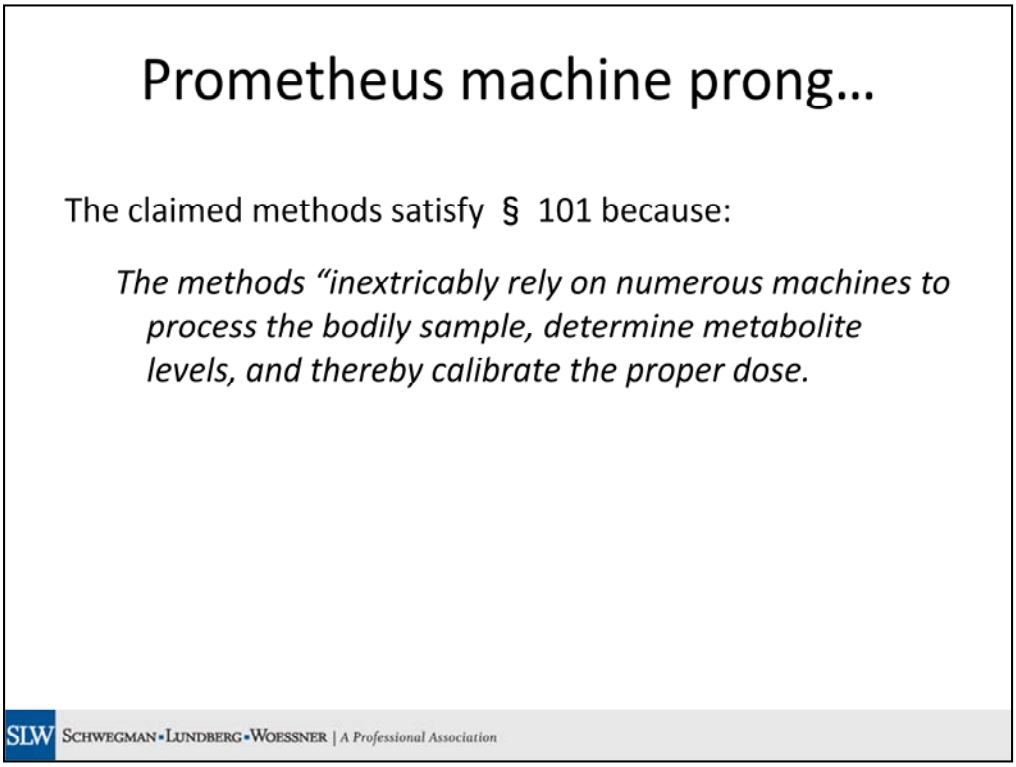
Considering the claim as a whole, including previously known elements, a method is patent-eligible if it:

- *is tied to a particular machine or apparatus, or*
- *transforms a particular article into a different state or thing*

So long as the tie to the particular machine or transformation that imparts patentability

- is central to the purpose of the method;
- imposes meaningful limits; and
- is more than mere insignificant extra-solution activity.

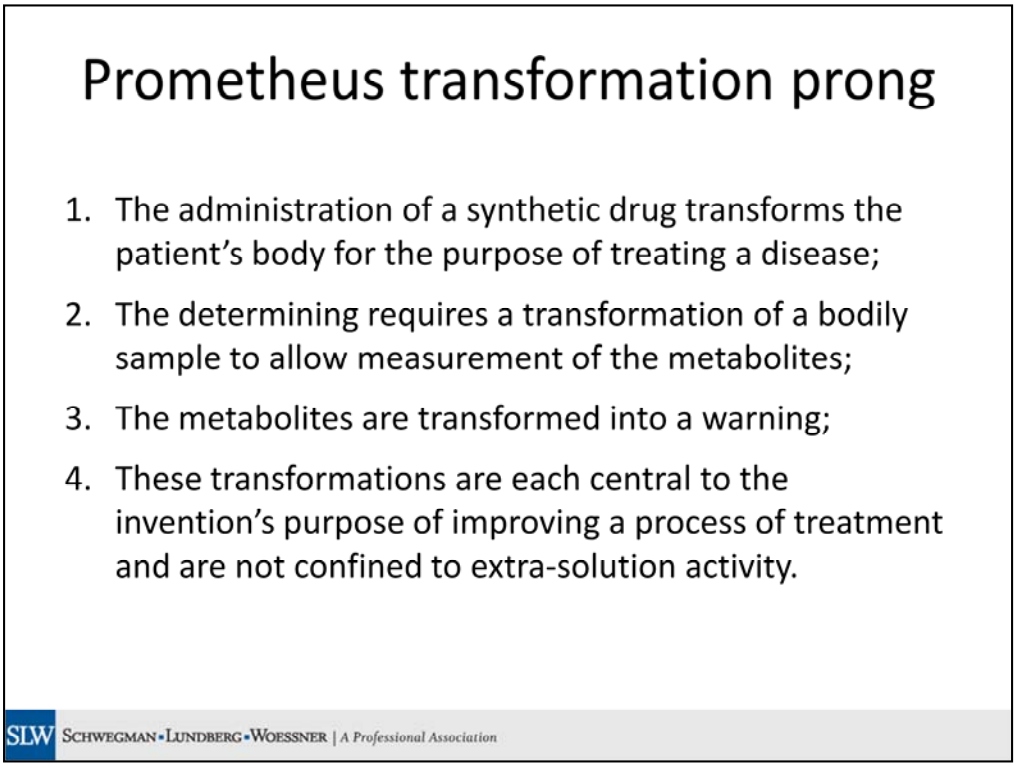
Prometheus argues…



Note: This is interesting because the claim provided above (slide 6) doesn't include any mention of a machine.

Note: However, a dependent claim did mention high pressure liquid chromatography which clearly requires the use of machines, but again, there was no machine recited in the claim

Note: nonetheless, this did not matter as the case was decided on the Bilski transformation leg of the M-or-T test



1. Administering

•Although the drug is transformed by the body's natural process, such transformation cannot be unpatentable because everything proceeds according to natural laws because everything conforms to natural laws

2. Determining

•The high pressure liquid chromatography

•All of several methods for determining metabolite levels in a bodily sample require a physical transformation of blood or human tissue

3. Metabolites

•Ultimate end of the method and the transformation of the administering and determining is to transform – and improve – the patient's treatment regimen while avoiding deadly side effects by transforming the metabolite levels into a warning regarding dosage.

Prometheus public policy argument

If not patent-eligible, the decision would have the effect of eliminating all medical and diagnostic patents, when future medical advances will depend on optimizing treatment based on genetic or other testing.

Mayo argues…

MAYO CLINIC

Mayo argues…

Preemption of the correlation;

Involvement of machines in the claims is insignificant-extra solution activity of data gathering using unspecified machines to correlate information;

Administering step is mere data gathering and not central to the purpose of the claim;

Although drugs are synthetic, body reaction is natural and the drugs are well known;

Mayo argues… (continued)

Determining step is mere data gathering necessary to any use of the correlations which are natural phenomena;

There is no transformation of data as the claims do not require any action to be taken to adjust dosage; and

The determining is a mental step.

Mayo public policy argument

Allowing such claims under § 101 is dangerous because infringement would occur any time the natural correlation was even considered by a physician.

Example Claim

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 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

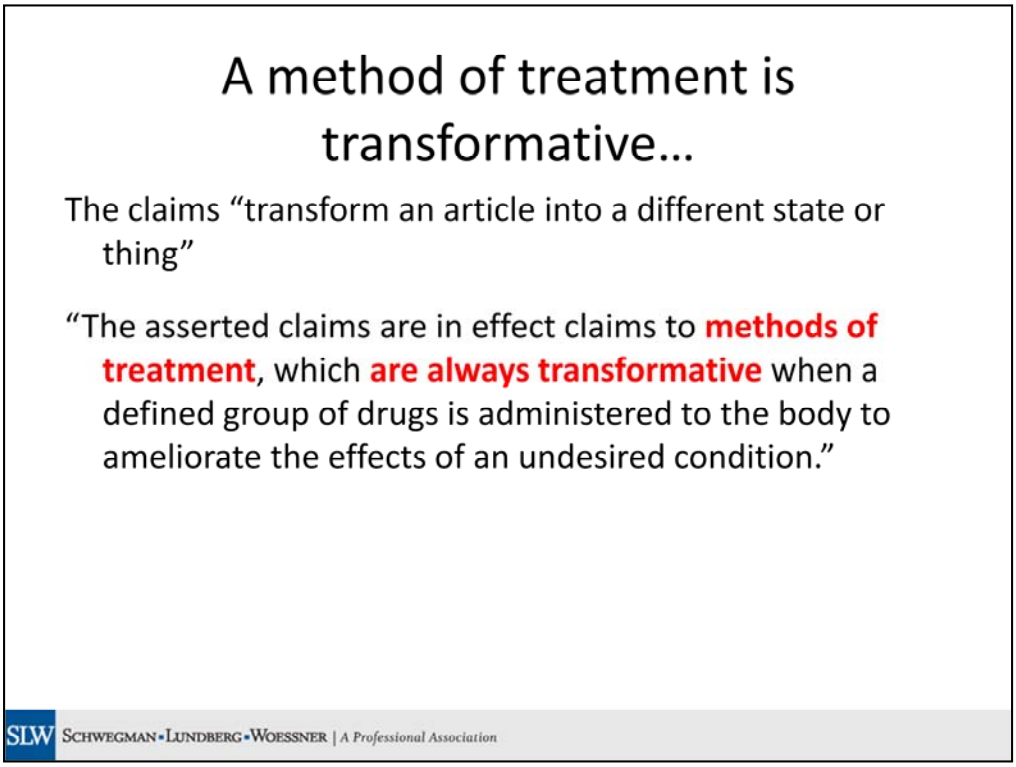
wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Mayo's public policy argument:

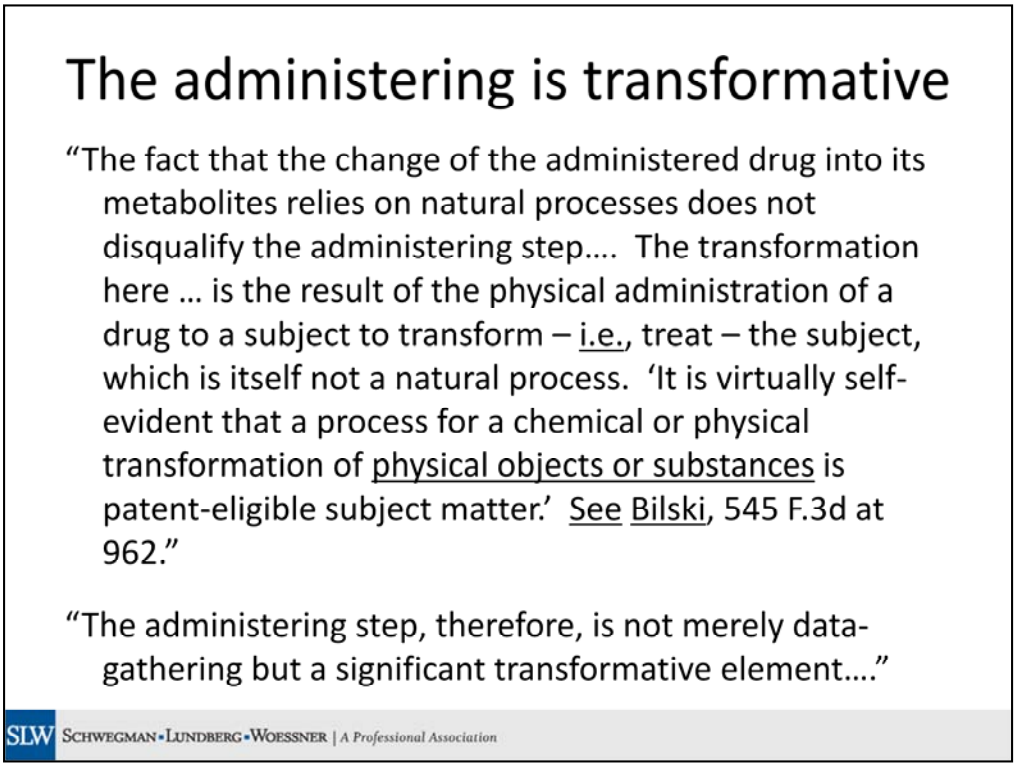
Allowing such claims under § 101 is dangerous because infringement would occur any time the natural correlation was even considered by a physician.

Mayo has a point here.

Federal Circuit Holding

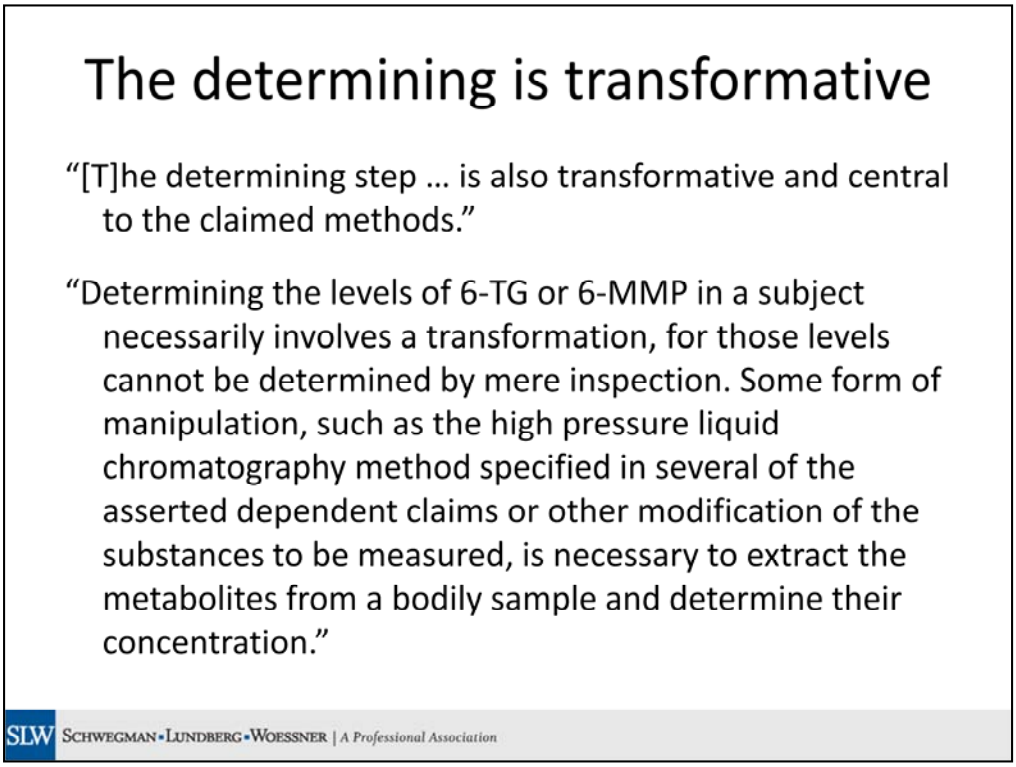


With that in mind, the court continues by telling us what the Administering and Determining steps really mean and include.



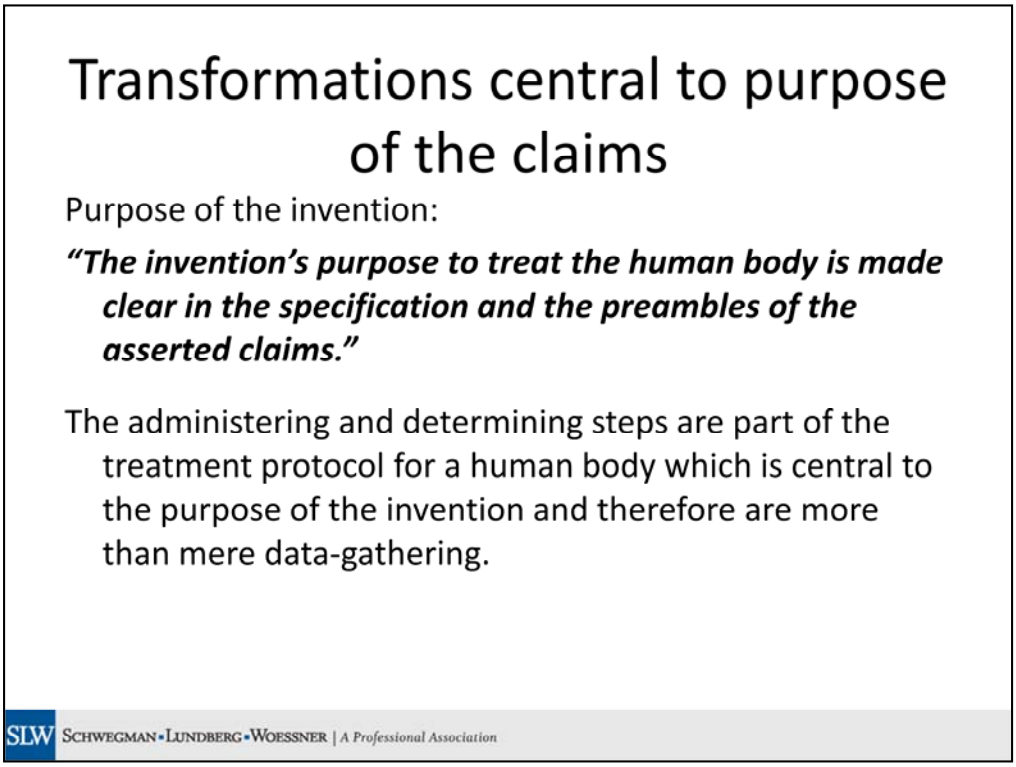
The "administering" results in a transformation of the human body and of the drug by the human body into metabolites.

Basically, it is inherent in the claim that the drug transforms the body and the body transforms the drug.



"As stated by Prometheus's expert, 'at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue.' Decl. of Dr. Yves Théorêt ¶ 6, Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04-CV-1200 (S.D. Cal. Mar. 29, 2007) (Dkt. No. 528-3). That is clearly a transformation."

The determining inherently requires the sample to be transformed because the metabolite level can only be measured by techniques that change the state of the sample.



"[T]his transformation is central to the purpose of the claims, since the determining step is, like the administering step, a significant part of the claimed method of treatment. Measuring the levels of 6-TG and 6-MMP is what enables possible adjustments to thiopurine drug dosage to be detected for optimizing efficacy or reducing toxicity during a course of treatment."

Prometheus is therefore patentable

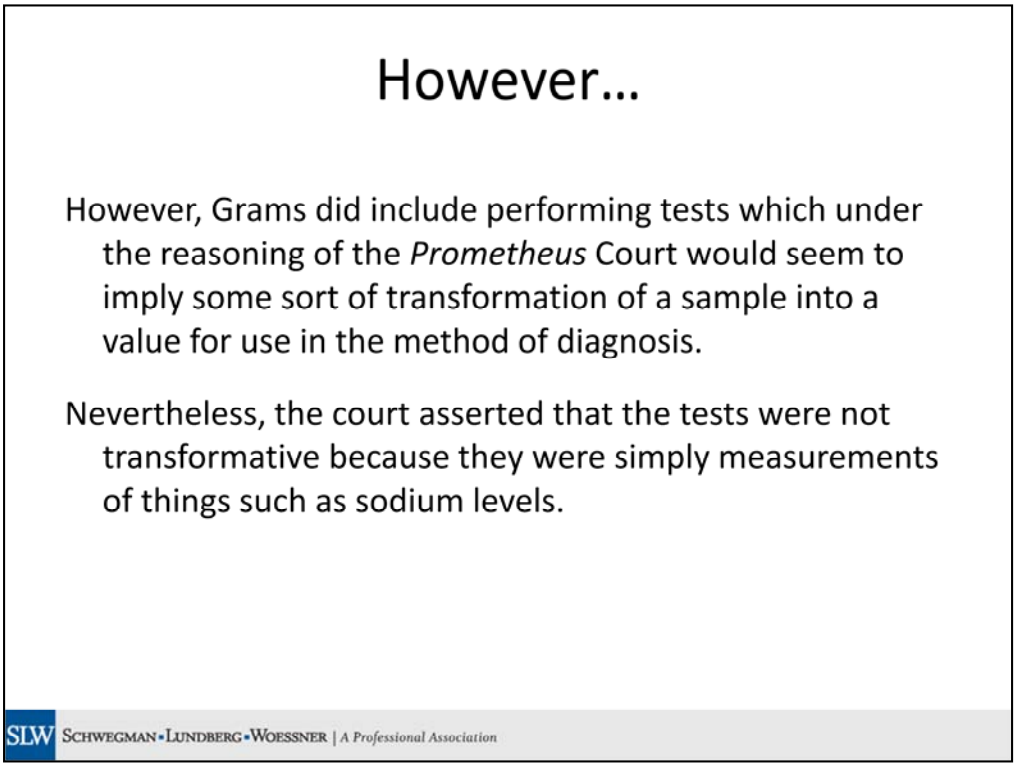
By importing elements into the claims that were considered to be inherent, such as the taking of a sample and the transformation of the sample via chromatography, the claims included a transformation and are therefore directed to patent-eligible subject matter.

But what about *In re Grams?*

In re Grams, 888 F.2d 835 (Fed. Cir. 1989)

Grams was essentially a method of diagnosis that included performing tests on a patient, determining if a condition existed, and identifying possible causes based on the test results.

Grams was found unpatentable because the essence of the claims was a mathematical algorithm, rather than any transformation of tested individuals.



In Prometheus, the test required a physical transformation of the sample rather than a direct measurement of the sample without first transforming the sample.

But think of litmus paper. Put a piece of litmus paper in a basic or acidic solution and the paper changes colors. Seemingly a transformation of a physical article. Use a probe of an electronic device and you get an LCD readout. Seeming just a "measurement." But what is really the difference?

I am skeptical of this distinction. It seems the transformation of the sample in Prometheus, at least based on Grams, would be insignificant extra-solution activity or data gathering necessary for the measurement of the metabolites of the sample. Whether you need to measure a sample at room temperature or after performing some elaborate transformative process, it is still a measurement of a sample. The claim of Prometheus was not directed to a mechanism that samples, it was directed at a decision based on test results from the sample. It seems that an otherwise unpatentable claim could become patentable simply by describing a different testing procedure in the specification. Although the result might be an impractical claim through inference of elements into the claim, the claim would still be conceivably patent-eligible. What happens when there is an advancement in technology that allows for a sample to be measured without a transformation that was previously required. Does the method then become unpatentable?

Lessons of *Prometheus*

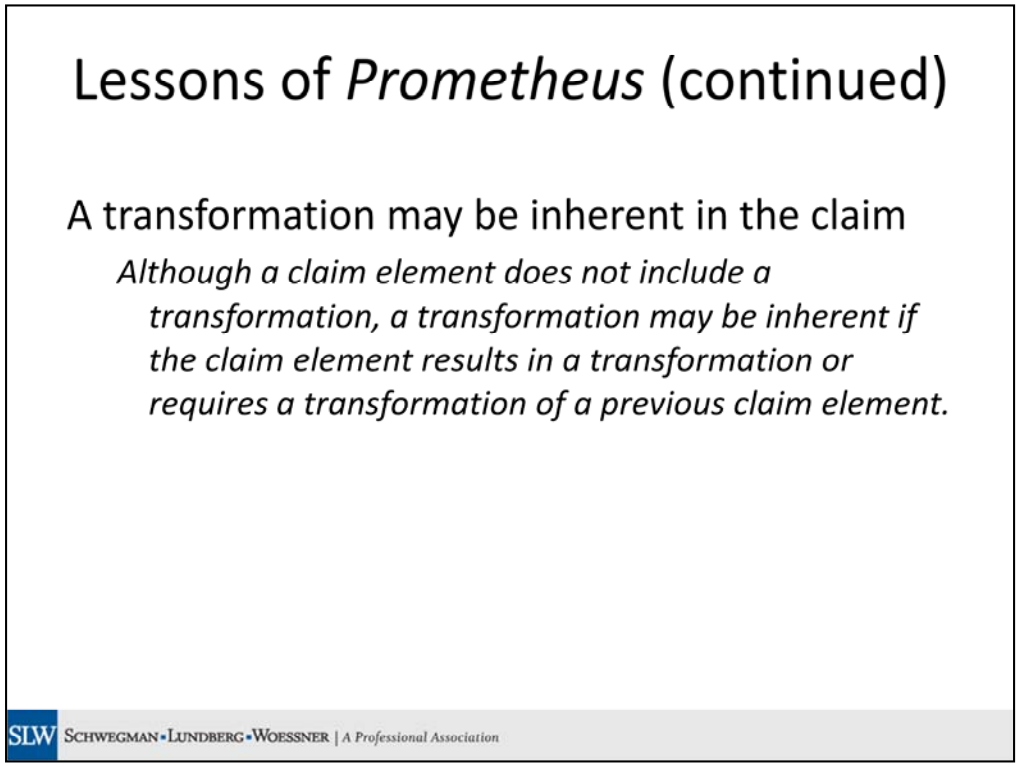
Under 35 U.S.C. § 101:

*Considering a method claim as a whole, **including inherent elements** and previously known elements, a method is patent-eligible if it:*

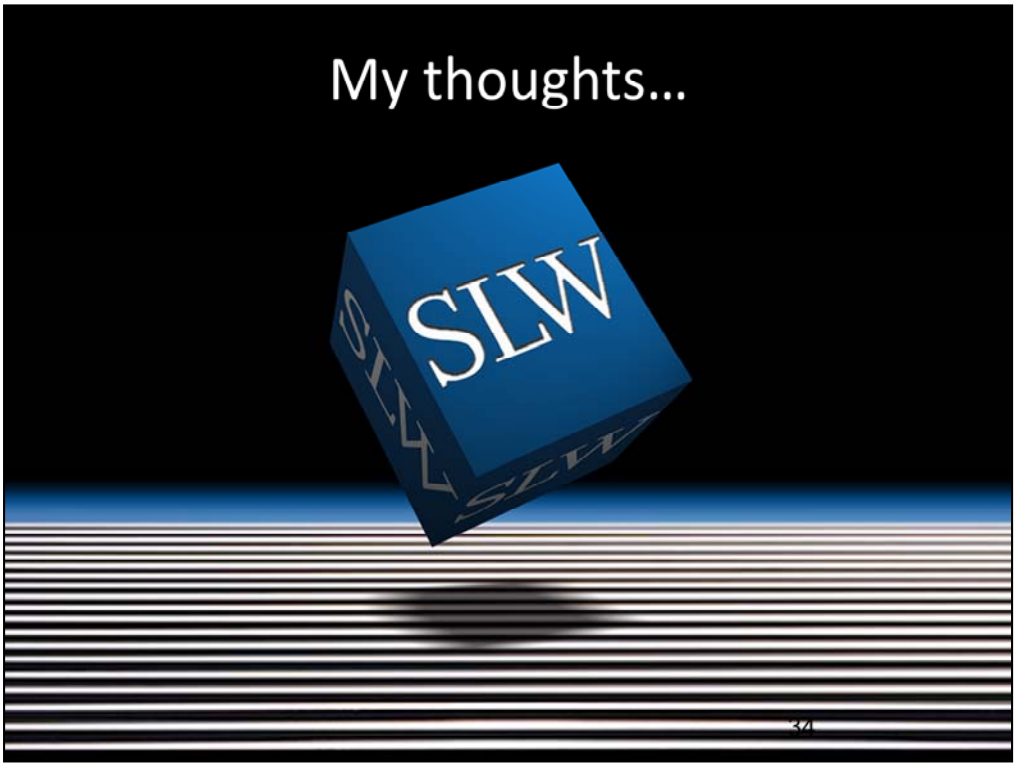
- is tied to a particular machine or apparatus, or
- transforms a particular article into a different state or thing

So long as the tie to the particular machine or transformation that imparts patentability:

- is central to the purpose of the claim;
- imposes meaningful limits; and
- is more than mere insignificant extra-solution activity.



i.e., administering a drug which is transformed by the body of the subject and the transformation of the health of the subject or a sample must be transformed to be measured for a claim element to be performed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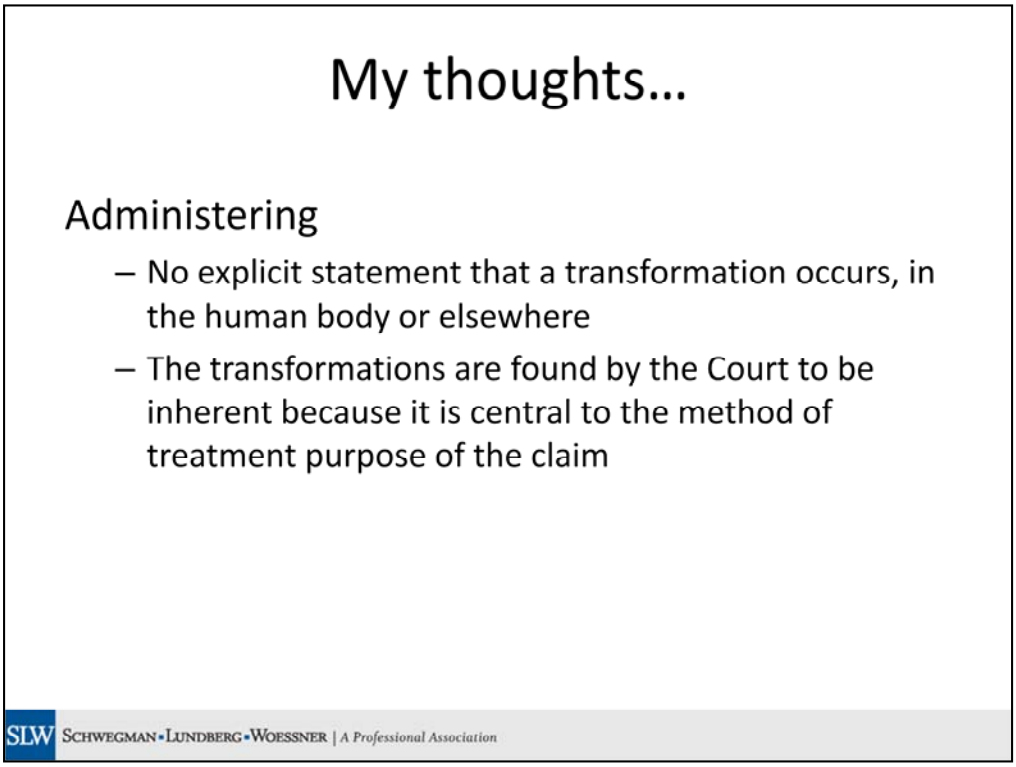
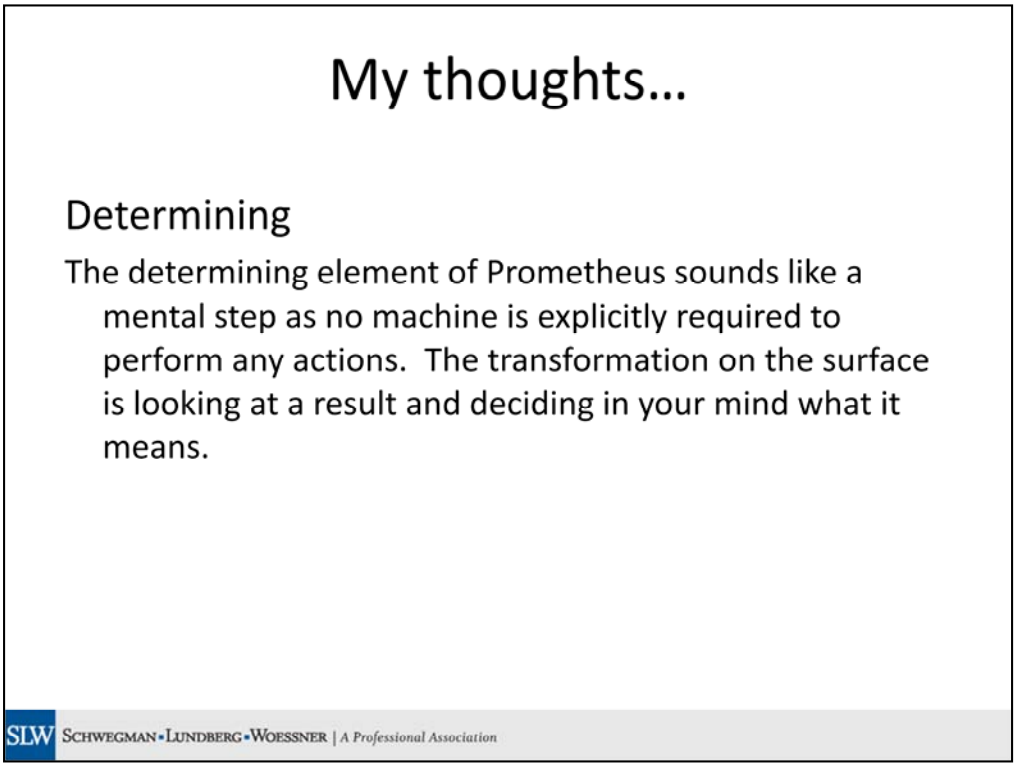


With applications drawn to computer implemented inventions, the administering sounds a bit like sending a data signal to be processed by another program. Sending data is not a transformation of the data. However, data may be transformed by a process the data is sent to and the transformed data may be sent back. ***The implication of Prometheus is that so long as the transformation performed by the remote process is central to the purpose of the claim, that transformation is inherent to the claim.***

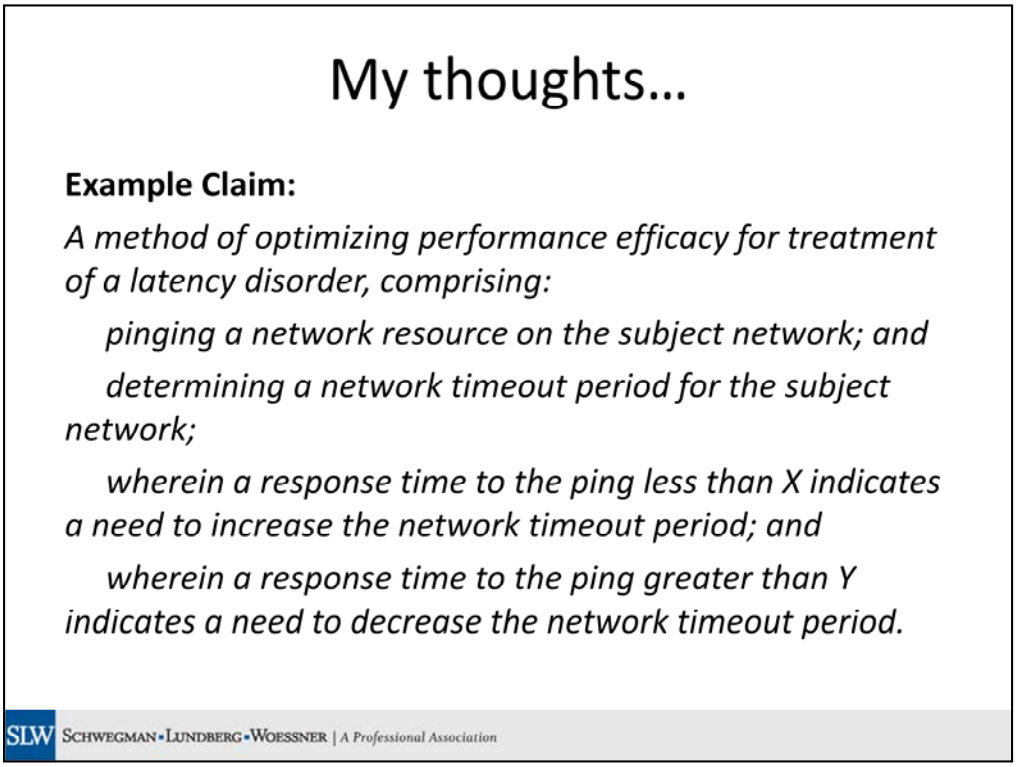
Under , the "Interim Patent Subject Matter Eligibility Examination Instructions" released by the USPTO on August 24, 2009, inferring a transformation is OK, so long as it is inherently in the claim based on the broadest reasonable interpretation of the claim.

From my experience, the broadest reasonable interpretation is used by examiners as needed to reject claims. If something is not in a claim but in the specification, the Examiner will refuse to import the element from the specification. The broadest reasonable interpretation will most likely be applied to encompass much more than you believe it should. What that includes is likely to provide for subject matter that is not patent-eligible and even if eligible, will import elements that assist the examiner in rejecting your claims under §§ 102 and/or 103.

Thus, I believe a claim relying on the administration step for the transformation is unlikely to be issued today, because the transformation at best is inherent in the claim and the broadest reasonable interpretation is most likely to be found in favor of a rejection under 35 U.S.C. §§ 101, 102, and/or 103.

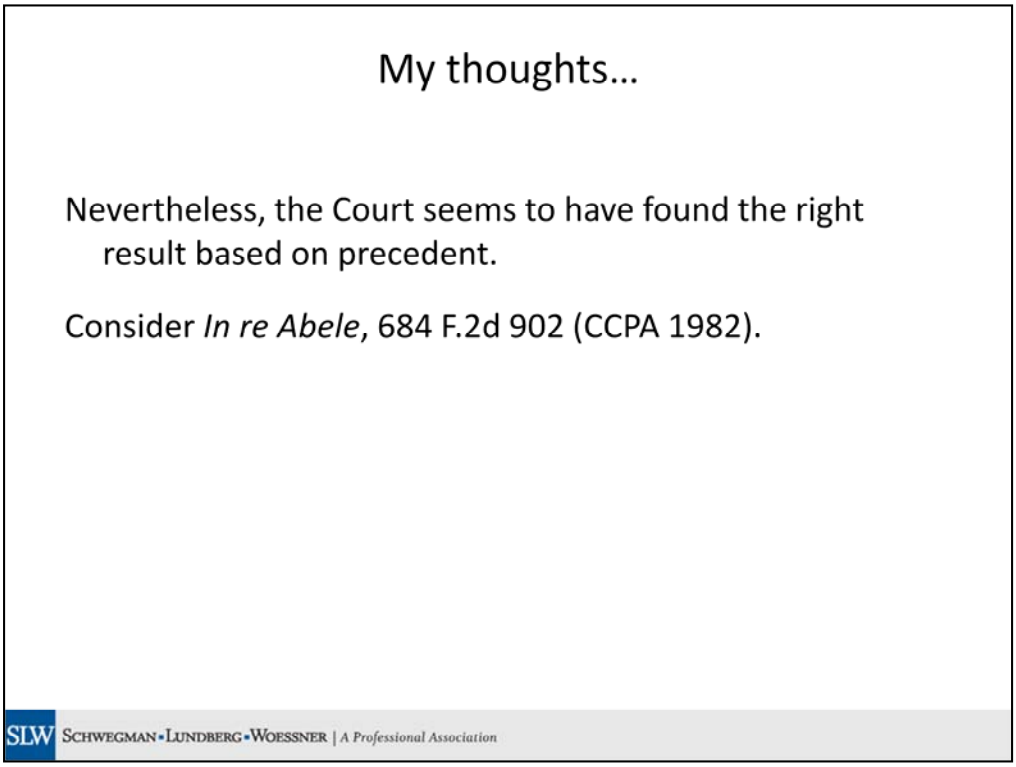


This again requires the examiner to find elements inherent to the claim such as high pressure liquid chromatography. But just like I said before, the broadest reasonable interpretation is likely to be applied against your interests in prosecution as you do have the ability to amend your claims to be explicit.



Following the reasoning of Prometheus, such a claim should be found patent-eligible.

The central purpose of the claim is to treat a network latency condition in a network. When considering that purpose, the pinging inherently involves a transformation of a signal into a measured value to set a network timeout period to transform the network by setting network timeout periods. Although the wherein clauses may constitute mental steps, when considering the claim as a whole, the claim includes a transformation of a network though a method of treatment.



Just because an Examiner doesn't consider a claim patent-eligible doesn't mean it isn't eligible. You just might need to go to the BPAI or the CAFC before attaining allowance.

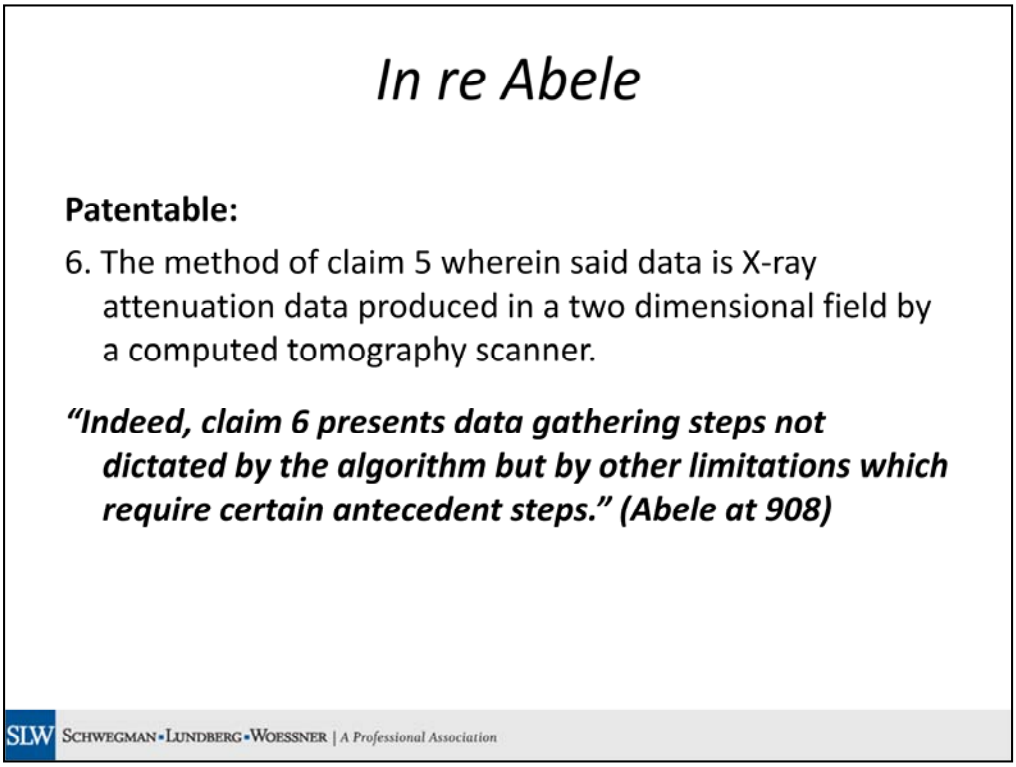
In re Abele

Unpatentable:

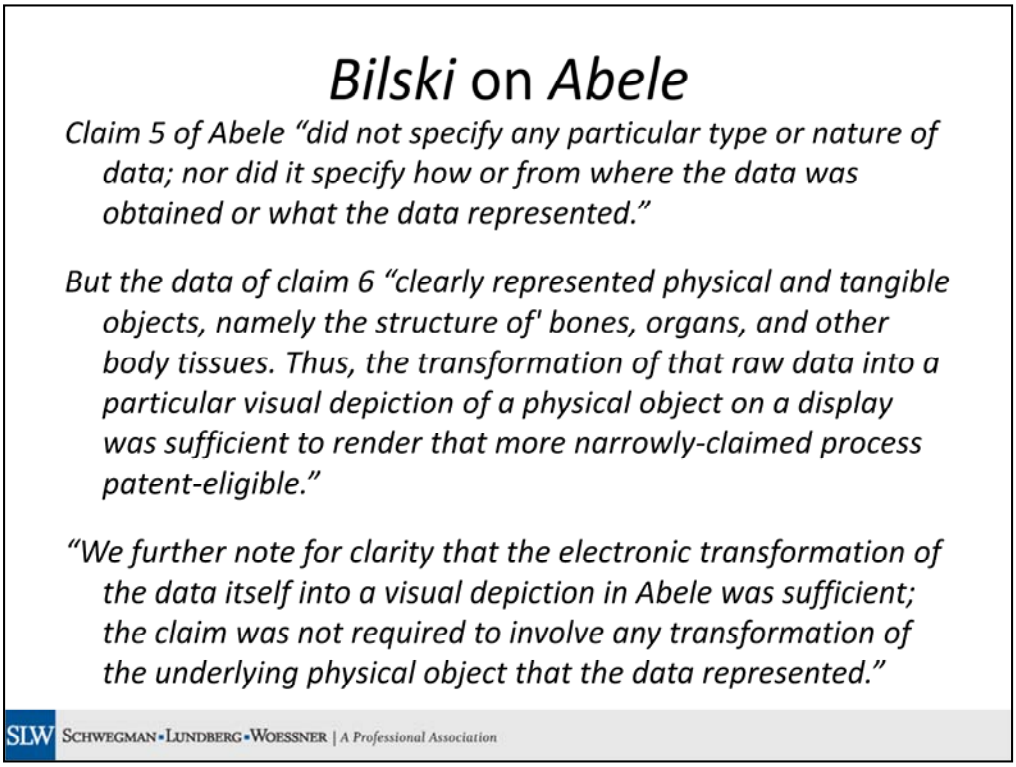
5. A method of displaying data in a field comprising the steps of:

calculating the difference between the local value of the data at a data point in the field and the average value of the data in a region of the field which surrounds said point for each point in said field, and

displaying the value of said difference as a signed gray scale at a point in a picture which corresponds to said data point.



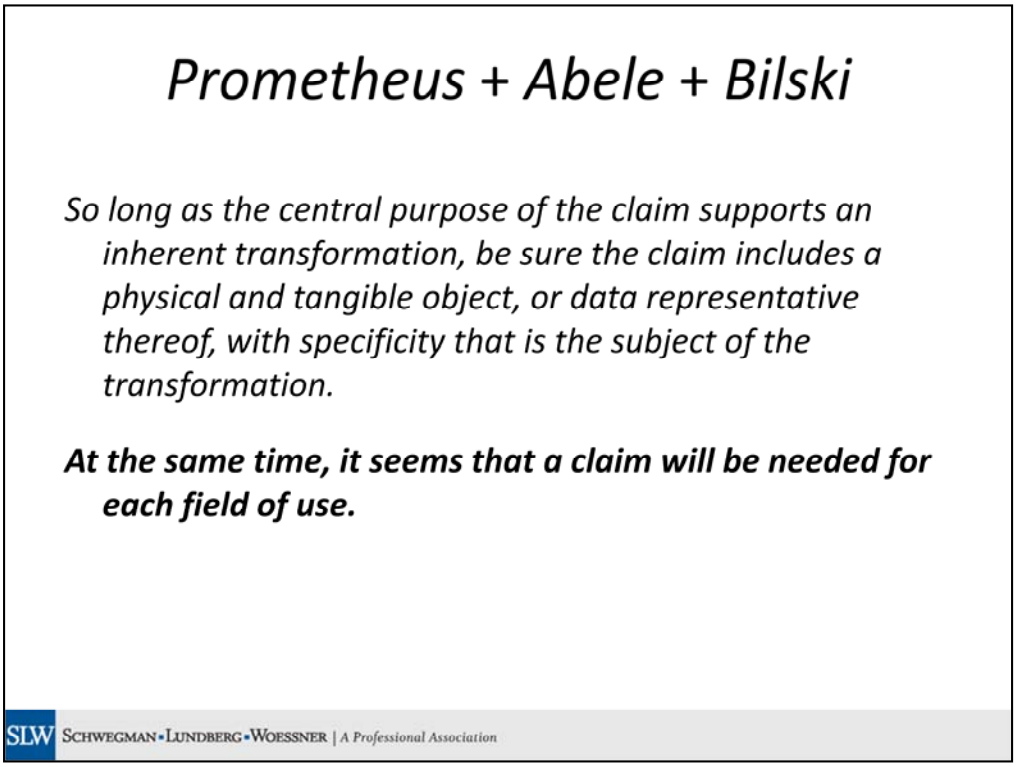
The required "certain antecedent steps" are inherent steps.



--But this is apparently dependent on the nature of the underlying data, as claim 5 was non-statutory

Consider a hypothetical for a modeling and simulation application that is used to model a potential airplane wing design and applies a simulation to that airplane wing design to determine if the modeled airplane wing is suitable for operation in its intended environment.

There is no actual physical or tangible object yet as the airplane wing has not yet been built. It seems logical that such a method would be patent eligible, but I am not sure. The current cases require that the transformation must be to a physical and tangible object.



For example, in Prometheus, the claim was specific as to the drug as one of providing 6-thioguanine, just as claim 6 of Abele was specific as to the X-ray attenuation data. If the claim of Prometheus was merely to a drug and determining a metabolite level in the subject, the claim would have been closer to claim 5 of Abele. Including the 6-thioguanine in the claim narrowed the method of the claim to a particular field of use of the 6-thioguanine.

Thus, if a transformation it to be implied, be clear about what is inherently transformed.

What is really going on?

Preferential consideration of methods of treatment versus computer implemented methods?

Remember the public policy argument of Prometheus

If the claims are not patent eligible, the decision would have the effect of eliminating all medical and diagnostic patents, when future medical advances will depend on optimizing treatment based on genetic or other testing.

Presumably, the Court agreed.

But I don't want inherent elements!

There are times when you want to claim a method without reciting certain elements to ensure your claim can be infringed by a single party.

But not so fast…

Under Prometheus, those elements may be inherent.

Then again, maybe I do want them.

If an element is inherent in a claim, the preamble and specification provide context and are logical places to look to find the inherent element.

The preamble and specification are intrinsic sources for purposes of claim interpretation and construction. Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005), cert denied, 126 S. Ct. 1332 (US 2006)(en banc); Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)(Specification "is always highly relevant to the claim construction analysis.").

Estoppel

Remember though, if you argue elements are inherent in the claims for purposes of overcoming a 35 U.S.C. § 101 issue, those arguments will most likely create estoppel when it comes time for the Markman hearing.

Inherent Elements of *Prometheus*

The following transformations, and therefore claim elements, were found by the Court to be present in Prometheus:

1. the transformation of the drug that is performed by the body of the subject and thus, by the subject;
2. the taking of a sample;
3. the transformation of the sample into a form that the metabolites could be measured; and
4. measurement of the metabolites.

These elements must be included in claim construction.

Now what did I do?

The claim is directed to eligible subject matter, but with all of these additional claim elements, who infringes the claim?

The players:

1. *the doctor writing the prescription;*
2. *the person administering the drug;*
3. *the person who's body transforms the drug;*
4. *the person taking the sample;*
5. *the person transforming the sample so the metabolites can be measured (i.e., a lab external to the hospital or clinic);*
6. *the person measuring the metabolites (i.e., a lab external to the hospital or clinic); and*
7. *the doctor performing the determining.*

Divided/Joint infringement?

With this many potential players, there is a possibility that the only claim for infringement would be under a theory of indirect infringement, such as divided/joint infringement.

Divided/Joint Infringement

Direct patent infringement requires a single actor to practice every element of a patent claim.

Indirect infringement, such as contributory infringement and inducement, also require underlying direct infringement by a single actor.

The single actor requirement is commonly expanded under agency theories as liability cannot be avoided by simply having someone else perform one or more steps of the method.

BMC Resources, Inc. v. Paymentech, L.P., 498 F.3d 1373 (Fed. Cir. 2007)

Courts faced with a DIVIDED INFRINGEMENT THERORY have generally refused to find liability where one party did not DIRECT OR CONTORL each step of the patented process.

"A party cannot avoid infringement, however, simply by contracting out steps of a patented process to another entity. In those cases, the party in control would be liable for direct infringement."

BMC v. Paymentech, (continued)

"This court acknowledges that the standard requiring CONTROL OR DIRECTION for a finding of joint infringement may in some circumstances allow parties to enter into arms-length agreements to avoid infringement."

"The concerns over a party avoiding infringement by arms-length cooperation can usually be offset by proper claim drafting."

BMC v. Paymentech, (continued)

Thus, divided infringement requires a showing that a single party performed or caused to be performed each and every element of the claim.

See also Muniauction, Inc. v. Thomson Corp. et al., 532 F.3d 1318 (Fed. Cir. 2008)("[W]here the actions of multiple parties combine to perform every step of a claimed method, the method is directly infringed ONLY if one party exercises 'CONTROL or DIRECTION' over the entire process such that every step is attributable to the controlling party, i.e., the 'mastermind'.").

Conclusion

Thus, even if you win the battle of patent-eligibility for your claim in prosecution or litigation through an inherent transformation in your claim, be careful about what or whom you are importing.

You may just end up with a claim that cannot be infringed.

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