OFFICE ACTION RESPONSE WORKSHOP – PART I

BIOTECH AND CHEMICAL

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- Restriction and Species Requirements
- Anticipation by Inherency
- Enablement and the "Biotech Squeeze"
- Obviousness: Reasonableness and Reason
- 101 Subject Matter (In)eligibility

RESTRICTION/SPECIES REQUIREMENTS

AND PROBLEMS

- Biotech applications usually receive multiple restrictions because of the types of claims usually involved. For example, the invention is a novel polypeptide that has activity against a given disease, thus the usual types of claims are directed to:
  - The polypeptide itself;
  - A nucleic acid molecule encoding the polypeptide;
  - An expression vector comprising the nucleic acid molecule;
  - A host cell comprising the nucleic acid molecule or expression vector;
  - A method of making the polypeptide;
  - A composition comprising the polypeptide;
  - Antibodies against the polypeptide; and
  - A method of treating a subject having the disease by administering the polypeptide or composition to the subject.

REQUIREMENTS FOR RESTRICTION

- Two or more "independent" or "distinct" inventions are claimed in one application
  - Independent = Unrelated, there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect.
  - Distinct = Can be related inventions, but, as claimed, they are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel and nonobvious) OVER THE OTHER.
- Serious burden on the Examiner
  - Shown by separate classification, or separate status in the art, or a different field of search

GENERAL PRINCIPLES OF DISTINCTNESS AND INDEPENDENCE

- A) Where inventions are independent (i.e., no disclosed relation therebetween), restriction to one thereof is ordinarily proper.
- (B) Where inventions are related as disclosed but are distinct as claimed, restriction may be proper.
- (C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper.
- (D) A reasonable number of species may be claimed when there is an allowable claim generic thereto.

AVOID:

- Restrictions by understanding the essence of the invention, i.e., the key element that makes the invention so great and distinguishes it from the prior art.
  - Draft the claims around the key element.
  - Structure the hierarchy of the claims such that the key element is required in all independent claims and their dependent claims.
- Having to file a divisional by requesting rejoinder when
  - Amending the unelected claims to depend on the elected claims
  - Selecting product claims and the unelected process claims require the use of the product
  - Never hurts to ask: often can rejoin after allowable claims ID'd

- Understand the difference between a RR and an Election of Species.
  - An Election of Species may turn into a RR where the prior art renders a species unpatentable.
- Traversal is necessary to preserve the right to petition.
  - However, avoid traversing an Election of Species as it requires admitting that the species are not patentably distinct.
    - This means if one species is unpatentable over the prior art, the other species are also unpatentable.

TRAVERSING

Restriction and Election of Species

- If the Examiner withdraws the RR and related claims are pursued in a continuing application, there may be an obviousness-type double patenting (ODP) issue that requires a Terminal Disclaimer (TD).
  - TDs may reduce patent term by reducing or eliminating any PTA that would otherwise be available.
    - So one might actually want a RR.
- Filing a continuation or CIP after a RR will lead to a loss of protection against ODP under 35 U.S.C. 121.
  - File the subsequent application as a "divisional" if a RR was received in the parent case.

PROBLEMS

ODP and TDs

ANTICIPATION

IS IT REALLY INHERENT? DOES IT MATTER?

INVENTORS TELL US ALL THE TIME

- I discovered a new property of this compound
- We didn't even know that it had this feature until we conducted further studies
- But the prior art doesn't mention anything about this characteristic

ANTICIPATION BY INHERENCY

- Discovery of an inherent property of an old composition does not make the old composition patentable. Atlas Powder v. Ireco, 190 F.3d 1342 (Fed. Cir. 1999)
  - But the lack of appreciation of the inherent property may help make a new use of the old composition patentable.
- Inherent anticipation does not require recognition by a PHOSITA at the critical date. Schering v. Geneva, 339 F.3d 1373 (Fed. Cir. 2003)
- Actual creation or reduction to practice is not necessary as need only an enabling disclosure. Schering v. Geneva, 339 F.3d 1373 (Fed. Cir. 2003)
- Trace amounts of a by-product and contaminant that *might* be present inherently anticipate claims to the by-product or contaminant. Smithkline v. Apotex, 403 F.3d 1331 (Fed. Cir. 2005)

SCHERING V. GENEVA
339 F.3D 1373 (FED. CIR. 2003)

- First patent was directed to loratadine (API in Claritin®,) second patent (>1 year) was directed to a metabolite of loratadine.
- The first patent disclosed administering loratine to patients.
- Since administration of loratine to patients necessarily results in the metabolite being formed, the first patent was found to inherently anticipate the metabolite claimed in the second patent even if it was not actually previously administered because all that is required is an enabling disclosure, not an actual reduction to practice.

SMITHKLINE V. APOTEX, 403 F.3D 1331 (FED. CIR. 2005)

- SKB had a patent claiming paroxetine HCl hemihydrate ("H", API in Paxil®), and Apotex filed an ANDA for the anhydrous form ("A").
- SKB submitted evidence that producing A will necessarily result in trace amounts of H and therefore Apotex's production of A will infringe its patent claims covering H.
- Seems SKB forgot about its really old patent covering A, such that SKB's own arguments and evidence backfired and resulted in their subsequent claims to H being invalid as being inherently anticipated.

- Burden
  - Anticipation requires each and every element.
  - Examiners must provide reason why an inherent feature necessarily flows from the prior art. In re Oelrich, 666 F.2d 578 (CCPA 1981), Ex parte Levy, 17 USPQ2d 1461 (BPAI 1990)
- Rebuttal
  - Use "If-Then" logic to explain the asserted inherent feature does not necessarily result.
    - Apples are fruits, but all fruits are not apples; Dropping an apple does not always result in the apple being bruised.
  - Each and Every Limitation - Point out limitations that are neither inherently nor expressly taught.
  - Add limitations to avoid inherency.

BURDEN AND REBUTTAL

Necessarily Flows

- HYPOTHETICAL
- Prior art: Antiviral A is a known therapeutic that has been used to treat hemorrhagic fever. Turns out that a subject that was administered Antiviral A also had cancer.
- Invention: Antiviral A has an inherent property, i.e., that it prevents abnormal cell proliferation when administered in a therapeutically effective amount.
- Claimed Invention: A method of treating cancer in a subject, which comprises administering to the subject Antiviral A.
- Inherent anticipation? What if:
  - The subject is "in need thereof"?
  - A "therapeutically effective amount" is administered?
  - Limited to a specific type of cancer?

INHERENCY CAN BE YOUR FRIEND

- A specification describing undisclosed yet inherent properties of an invention can be sufficient written description for an explicit recitation of the inherent properties. Kennecott v. Kyocera, 835 F.2d 1419 (Fed. Cir. 1987), Yeda Research v. Abbott (Fed. Cir., Sept 20, 2016)
- In Yeda Research:
  - Claimed Invention: A purified and isolated protein having a MW of about 42 kDa and at the N terminus the sequence Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Set Thr Cys Arg Leu Arg Glu …
  - Priority document (PD) did not disclose the full sequence, instead it disclose a partial sequence, a protocol for obtaining, MW, biological activity, and other characteristics.
  - Caution: Undisputed that the claimed protein is exactly the same as that of the PD. Thus, distinguished from Hyatt v. Boone, 146 F.3d 1348 (Fed. Cir. 1998) and In re Wallach, 378 F.3d 1330 (Fed. Cir. 2004).

INHERENCY AND OBVIOUSNESS

- Inherency can be used to render claims obvious, but it is a high burden. Par Pharm v. TWI, 773 F.3d 1186 (Fed. Cir. 2014)
- However, later discovered inherent properties cannot be used to prove non-obviousness. BMS v. Teva, 769 F.3d 1339 (Fed. Cir. 2014)

ENABLEMENT

CAN BE YOUR FOE OR FRIEND

THE ENABLEMENT REQUIREMENT

- TEST: Whether a PHOSITA could make or use the invention based on the specification coupled with information known in the art without undue experimentation.
- Wands Factors:
  - Claim breadth;
  - Nature of the invention;
  - State of the prior art;
  - Level of one of ordinary skill;
  - Level of predictability in the art;
  - Amount of direction provided by the inventor;
  - Existence of working examples; and
  - Quantity of experimentation needed to make or use based on the content of the disclosure.

LACK OF ENABLEMENT

- Usually the result of overly broad claims, i.e., full scope of the claim is not supported by the disclosure.
  - Only experiments provided relate to Parkinson's, but claim is to treating *all* neurodegenerative diseases including Alzheimer's.
  - But if experiments relate to a shared biochemical pathway, might get a method of treating a ND which comprises, e.g., inhibiting the biochemical pathway by…
- Inability to prove a negative, e.g., impossible to prove that an animal model will not develop cancer as a result of treatment.
  - Can't get claims to "preventing" cancer, but can to "treating" cancer.
- Lack of an accepted animal model
  - Multiple Sclerosis and EAE animal model

ENABLEMENT AS A FRIEND

- To be an anticipatory, a prior art reference must be enabling. In re Hoeksema, 399 F.2d 269 (CCPA 1968)
  - XOM™, custom reagent, not publicly available, not a sale, no disclosure of ingredients = non-enabling = no 102
- But a reference that lacks an enabling disclosure may qualify as prior art for an obviousness rejection for all that it discloses. Beckman v. LKB, 892 F.2d 1547 (Fed. Cir. 1989)
  - The combination with other references does not enable one to make and use the claimed invention if one does not have XOM™ or know its ingredients = no 103

- The "Biotech Squeeze" is where a claim is rejected under both 112 and 103 as lacking enablement and also being obvious.
  - Means the claimed invention is not enabled, yet a PHOSITA would have obtained the invention with a reasonable likelihood of success.
- Scream when you get this rejection… Then breathe.
  - Imho, there is never a "proper" squeeze… if a decently drafted claim.
- Evaluate the claim scope and spec objectively, and amend if needed.
  - If prior art teaches or suggests the claimed invention "as a whole", i.e., claimed invention lacks something special = 103
  - If prior art lacks something special then ≠ 103, and
    - If spec provides something special ≠ 112
    - If spec doesn't provide something special = 112

ENABLEMENT REJECTIONS

And the 112/103 Biotech Squeeze

- Exercise extreme caution, especially when attempting to overcome with arguments without amendments.
  - Can be a damned if you do, damned if you don't situation
  - Interview the examiner – The examiner can be your friend
    - Sometimes the fix is a simple amendment that doesn't impact the client's desired claim scope.
- Emphasize the key limitation the prior art doesn't teach or suggest and explain why it is sufficiently enabled.

- HYPOTHETICAL
- Prior art: Family of peptides having 95% homology to each other are active against Disease D. Peptide P is particularly effective at Dose D. Peptides <95% homology = inactive.
- Invention: The same peptides having a C9 substitution have in vitro activity at half the dose of Peptide P. Exemplifies Peptide N = Peptide P with C9. No in vivo data.
- Claimed Invention: A method of treating Disease D in a subject, which comprises administering a peptide having 90% homology to Peptide P to the subject.
- 103 and/or 112?
  - 90% homology to Peptide N with C9?
  - 95% homology to Peptide N?
  - Therapeutically effective amount?
  - What if the in vitro test is not an accepted model for in vivo activity?

OBVIOUSNESS

REASONABLENESS AND THE PROBLEM IS THE REASON

- Basic structure of an obviousness rejection:
  - A PHOSITA would have done X because Y in order to obtain Z with a reasonable expectation of success.
- A *prima facie* case of obviousness requires:
  - PHOSITA
    - What is the art?
    - What is the level of one of ordinary skill?
  - Reason Why (Y)
  - To do What (X)
  - To obtain Z, the claimed invention
    - "As a Whole"
  - Reasonable Expectation of Success
    - Predictability
    - At the time of the invention (pre-AIA) or effective filing date (FITF)

- Attack the Motivation:
  - The proposed modification cannot render the prior art invention being modified unsatisfactory for its intended purpose.
  - The proposed modification cannot change the principle mode of operation of the prior art invention being modified.
- Attack the Result:
  - Even if modified or combined as proposed, the modification or combination does not result in the claimed invention "as a whole".

STRONGEST 103 ARGUMENTS

Attack the Motivation or the Result

REASONABLENESS

- A reasonable expectation of success is required for obviousness.
  - Determined at the time of the invention (pre-AIA) or effective filing date (FITF).
  - About obtaining the claimed invention not the intended operation of the combined references. Intelligent Bio-Systems v. Illumina (Fed. Cir. 2016)
- 103 rejections typical for treatment claims
  - Using a drug having properties similar to another drug for the same indication
  - Using a drug for a new indication that is similar to a known indication for the same drug

- Attack the Reasonableness: Use the high level of unpredictability in the biotech arts to your advantage and support with evidence.
  - Similar drug for same indication
    - Provide evidence, e.g., scientific article, showing claimed drug and prior art drug do not both work for a different indication.
  - Same drug for similar indication
    - Provide evidence that another drug does not work for both the claimed indication and the prior art indication.
- Be careful as arguments and evidence of unpredictability may make the case for lack of enablement.

OVERCOMING PREDICTABILITY

High level of unpredictability in the biotech arts

- European "Problem-Solution Approach"
  - Those skilled in the art would not have solved the given problem in the same manner.
- But we have KSR and the problem can be the reason for the solution as claimed.
  - Obvious to apply a solution to a similar problem in a completely unrelated field. In re ICON, 496 F.3d 1374 (Fed. Cir. 2007)
  - Obvious where known problem was the motivation. Dome v. Lee, 799 F.3d 1372 (Fed. Cir. 2015)
  - Unobvious where unrecognized problem. Leo v. Rea, 726 F.3d 1346 (Fed. Cir. 2013)

AVOID MAKING THE PROBLEM THE MOTIVATION

The problem can be the reason


101
is
the
new
103

(IN)ELIGIBILITY

BARF – BOGUS ARBITRARY REJECTION FOREVER

WELL-UNDERSTOOD, ROUTINE, AND CONVENTIONAL

- Analysis is a watered-down subjective version of an obviousness analysis
  - Doesn't require a person of "ordinary skill"
  - Unclear as to the scope of the art
  - So-called "as a whole" analysis considers limitations *apart from* those involving the asserted judicial exception (JE). GTL v. Merial, 818 F.3d 1369 (Fed. Cir. 2016)
  - Discovery of unknown property can be the reason why a novel combination of steps is conventional. Ariosa v. Sequenom, 788 F.3d 1371 (Fed. Cir. 2015)
- Consequently, a claimed invention can be unobvious under 103, but lack inventiveness under 101.

STEP ONE

Is it directed to law of nature, natural phenomenon or abstract idea?

- Argue and/or amend to stay out of Mayo/Alice Two-Step!
- Direct claim to method of performing an assay
- Claim the kit used to perform the assay
- Avoid mentioning the natural principle
- Study and follow the USPTO Guidelines & Examples

STEP TWO

Is it *REALLY* routine & conventional?

- Has the exact same assay been performed on the same samples using the same reagents in the same sequence?
- If the context (selection of subject, sample, etc.) differs, you may be able to argue that it's not routine & conventional as claimed.
- Consider narrowing limitations that won't hurt client's objectives

STEP TWO

Give it "something more"!

- Consider whether a feature that relates to the inventive concept can be added to the claim.
- Add a treatment step that would not have been used in combination with "routine & conventional" assay.
  - Or direct the claim to treatment that is contingent on assay results
- May be difficult to enforce, but could be better than nothing in some cases

- Remember the Examiner has the initial burden, so push back when no evidence that, e.g., a product naturally exists.
- Present the claimed invention as a technological improvement to the functioning of a thing itself.
- Argue the ordered combination is unconventional if the individual elements are known.
- Push back when an Examiner asserts that a given step can be performed solely in the mind when it can't.
  - If a given step can be performed solely in the mind, add limitations so it can't.

RECOMMENDATIONS

AVOID:

- Conceding that a claim is "directed to" a judicial exception .
- Indicating that certain elements are well-known, conventional, or routine.
- Relying on intended use.
- Relying on structural limitations that are well-understood, routine, or conventional.
- Functional limitations
  - Consider it lucky if functional limitations are ignored as non-limiting (i.e., insufficient to make generic structure a specific and unconventional device) as functional limitations may likely result in invalidity under 112.

HIT THE ROAD

just Roll Over And Die

- THANK YOU!
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Suzannah practices all aspects of intellectual property law including patent preparation, and prosecution, licensing, opinion work, strategic planning, and client counseling relating to diverse technologies including biochemistry, molecular biology, pharmaceuticals, microfluidics, diagnostics, medical devices, and nanotechnology.

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