

THE DOCTRINE OF INHERENCY AND THE ACCIDENTAL RESULT EXCEPTION

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I. INTRODUCTION AND OVERVIEW

The doctrine of inherency, and its even more shy and retiring cousin, the accidental result exception, represent two of the most difficult substantive principles of U.S. patent law, not so much conceptually as to where, when and how they might apply. The reason for this may lie in their very nature: the circumstances in which inherency and accidental result might have a role to play do not always, and oftentimes only rarely, call attention to themselves. Inherent disclosure, and even more so, accidental result, prefer to dwell in the shadows and will only reveal themselves when made to do so, usually to the apprehension of patent applicants and patent owners who will then have to somehow deal with their potentially claim-destroying effects.

In this brief presentation, we will be casting light on the doctrines of inherency and accidental result with the goal of examining their inner workings and with the aid of some hypothetical cases, illustrating where, when and how these principles might affect outcomes in the courts and in the USPTO.

A. DOCTRINE OF INHERENCY

- The legal concept of "inherency", or "inherent disclosure", in U.S. law developed in response to the universal recognition that the express description of an "action" or "thing", be it a process or method, composition of matter, chemical compound, substance, material, product, article or manufacture, device, machine, apparatus, structure, etc., includes the necessary and inevitable results of the "action" and the innate properties, functions and advantages of the "thing" whether known or unknown.

- The doctrine of inherency in U.S. patent law equates an inherent disclosure with an express disclosure, most often for the purpose of evidencing lack of novelty/anticipation when embodied in a prior art publication or prior art event such as a prior use, prior sale or offer of sale, but occasionally for establishing compliance with the written description and enablement requirements of the patent statute when embodied in the specification of a patent application.

I. INTRODUCTION...continued

- The "doctrine of inherent anticipation" is the doctrine of inherency in its role as novelty-destroying prior art.
- Under U.S. law, one cannot obtain a valid claim to an invention that differs from the prior art only in the recitation of an inherent property, feature or result.
- There is no requirement that the inherent disclosure of a property, feature or result be recognized or apparent to one skilled in the art for the inherent disclosure to function either as novelty-destroying prior art or as support for claimed subject matter.
- Inherency is a question of fact and like any other fact needs to be proven, either by intrinsic or extrinsic evidence.
- The European Patent Office (EPO) Guideline for Examination, Part G (Patentability), Chapter 6(Novelty) and Part H (Amendments and Corrections), Chapters IV and V (Allowability of Amendments) recognize legal principles that are similar to the U.S. law of inherency. A comparison of the U.S. and EPO law, while interesting, is beyond the scope of this presentation.

I. INTRODUCTION...continued

B. THE ACCIDENTAL RESULT EXCEPTION TO INHERENCY

- The doctrine of accidental result is a seldom encountered but long-established principle of U.S. patent law. According to this doctrine, an accidental result will rule out a finding of anticipation of claimed subject matter where it is shown that the result, although inherently disclosed in the prior art, when first achieved was unintended and unappreciated and only later recognized.
- The policy rationale for the doctrine of accidental result in U.S. patent law is the lack of assurance that the public will ever gain access to a result that is unrecognized and, consequently, realize any of its benefits or advantages.
- The doctrine of accidental result can only come into play where a particular result, at first unappreciated and unintended and only later recognized, is shown to be an inherent result, i.e., is shown to be a necessary and inevitable result of doing what the prior art expressly discloses. Unless a result is first shown to be an inherent result, there can be no basis for considering the application of the doctrine of accidental result.
- Under the doctrine of accidental result, where a particular result has been shown to be an inherent result, but one that was originally unappreciated and unintended, such result cannot serve as prior art that would anticipate the subject matter of a claim and defeat the patent rights of one who, though later in time, was the first to recognize the result.
- Symmetrical application of the doctrine of accidental result would presumably preclude a finding of inherent support for a claim where such support is based on an accidental result that is only later recognized. A case addressing this scenario would appear to be one of first impression.

I. INTRODUCTION...continued

- Later recognition of an accidental result has no nunc pro tunc effect, either as prior art or as support for a claim.
- Amending a pending patent application to disclose and claim a recently recognized accidental result would violate the prohibition against the introduction of "new matter" in 35 U.S.C. § 132(a). Unless time-barred, applicant may file a continuation-in-part (CIP) or original application disclosing and claiming a later recognized accidental result.
- The broadening reissue of an original patent to capture a later recognized accidental result is precluded by the prohibition against the introduction of new matter in 35 U.S.C. § 251(a).

C. A CONCISE STATEMENT OF THE DOCTRINE OF INHERENCY AND ACCIDENTAL RESULT EXCEPTION

The case law relating to the doctrine of inherency and accidental result exception may be distilled down to the following formulation:

According to the doctrine of inherency, an inherent disclosure is one that necessarily and inevitably follows from an express disclosure and provided that the inherent disclosure is not one of accidental result, i.e., that it is not an unintended and unappreciated result, it is equivalent to an express disclosure for all purposes including support for the subject matter of a claim and prior art that by itself or in combination with other prior art evidences the unpatentability of a claim in an application or the invalidity of a claim in a patent.

I. INTRODUCTION...continued

D. SOME INTERESTING QUESTIONS

1. The Doctrine of Inherency

- Are there any circumstances in which an inherent result will not be given the same effect as an express disclosure?
- How many replications of an experiment are required to demonstrate that an allegedly inherent result invariably or inevitably happens? Will one or just a few unsuccessful experiments out of many preclude a finding of inherent result?
- Will inherent disclosure contained in a publication that has been properly incorporated by reference in the specification of an application provide 35 U.S.C. § 112 support for a claim? Will such inherent disclosure in the issued patent constitute prior art to a later claimed invention?
- Does the standard for determining the adequacy of an inherent disclosure differ depending on whether the result is one of compliance with the written description and/or enablement requirements of 35 U.S.C. § 112 or one of prior art under 35 U.S.C. §§ 102 and 103?
- Does the doctrine of inherency also apply to evidence that a claim is invalid for lack of enablement under 35 U.S.C. § 112(a)?
- May one rebut a presumption of obviousness based on an undisclosed advantage of claimed subject matter?

2. The Accidental Result Exception to Inherency

- May an accidental result be relied upon as support for a claim?
- May the first to recognize and appreciate an accidental result X be entitled to a patent with a claim to X of “comprising” scope?

II. THE CATEGORIES OF INHERENTLY DISCLOSED SUBJECT MATTER

A. INHERENT PROPERTY, QUALITY OR CHARACTERISTIC OF A SUBSTANCE OR MATERIAL

- Physical and chemical properties of a pure chemical compound such as its melting, freezing and boiling points, density, refractive index, solubility characteristics, ionization constant, ionization energy, electrical and thermal conductivity, structural formula, presence of optically active centers, IR and UV absorbance spectra, NMR data, crystallographic data, pH data, stability, reactivity of functional group(s), storage stability, etc.
- Physical and chemical properties of synthetic polymers such as weight average molecular weight (M_w), number average molecular weight (M_n), polydispersity (M_w/M_n), glass transition temperature (T_g), melt flow rate (MFR), density, tensile strength, elasticity, compression strength, X-ray diffraction data, solubility and swelling characteristics, chemical reactivity/inertness, optical properties, etc.
- Physical and chemical properties of biomolecules such as proteins, carbohydrates, lipids, nucleic acids, metabolites, natural products, etc.
- The pharmacokinetic and pharmacodynamic profiles of known drugs used for their known drug actions.

II. THE CATEGORIES OF INHERENTLY DISCLOSED SUBJECT MATTER...continued

- Physical, mechanical and chemical properties of metals and metal alloys such as coefficient of expansion, melting point, density, tensile strength, elasticity, slip, creep, fatigue, ductility, malleability, corrosion resistance, heat resistance, electrical and magnetic properties, crystallographic properties, etc.
- Physical, mechanical and chemical properties of ceramics and glasses such as melting point, crystallinity, elasticity/plasticity, tensile strength, compressive strength, shear strength, hardness, fracture toughness, ductility, expansion coefficient, electrical and thermal conductivity, optical properties, chemical reactivity/inertness, etc.
- Physical, mechanical and chemical properties of composites such as cermets, concrete, reinforced polymers, metal composites, ceramic composites, etc.
- **Note:** While a known substance, material, chemical compound, composition, polymer, metal, metal alloy, ceramic, glass, etc., includes its inherent properties, qualities and characteristics whether known or unknown, a **new use** of a known material, even one that exploits an inherent property of a known material, is **not an inherent property** although it may have a bearing on the question of the obviousness of the new use.

II. THE CATEGORIES OF INHERENTLY DISCLOSED SUBJECT MATTER...continued

B. INHERENT PROCESS/METHOD EMBODIED IN THE USE OR OPERATION OF A COMPLEX MACHINE

- The description of a complex machine (inclusive of mechanical, electrical, electromechanical, chemical, computer/software-controlled, etc., devices, apparatus, systems, etc., having coacting components) that carries out individual actions or operations can also be regarded as the description of a process/method with each action or operation of the machine constituting a step of the process/method.
- While a process/method may be inherent in the disclosure of a machine, the reverse is not necessarily true, i.e., a process/method does not necessarily and inevitably describe a particular machine for carrying out the process/method.

C. INHERENT ADVANTAGE OR BENEFIT

- If an unstated advantage or benefit necessarily and inevitability follows from subject matter expressly disclosed in the prior art, i.e., if the advantage or benefit is inherent in what the prior art discloses, recitation of the advantage or benefit in a later claim to that subject matter will not avoid inherent anticipation.
- An inherent advantage or benefit of a claimed invention may be relied upon to overcome a rejection based on obviousness.

II. THE CATEGORIES OF INHERENTLY DISCLOSED SUBJECT MATTER...continued

D. INHERENT RESULT

- An inherent result is one that necessarily and inevitably flows from a particular action (inclusive of a series or complex of individual actions or operations).
- The action that brings about an inherent result may be embodied, e.g., in the step(s) of a process/method, the description of a working example illustrating the preparation of a substance or material, the normal or indicated operation of a machine, etc.

1. Recognizable Inherent Result

- A recognizable inherent result is one that is either apparent or inferable from what is expressly disclosed.
- A recognizable inherent result generally requires relatively little in the way of proof in order to be established as fact. Expert testimony, science and engineering textbooks, etc., will often suffice to establish both the existence and the particular content of a recognizable inherent result.

HYPOTHETICAL CASE 1

A known process for making X produces considerable exotherm within the reactor. The process includes a step of recycling a portion of X back to the reactor to make more X.

COMMENT

Although there is no express disclosure that recycled product X also functions as a heat sink to prevent excessive temperature buildup in the reactor, one knowing the physical laws at work would recognize that the heat sink function is an inherent result of the recycling step.

II. THE CATEGORIES OF INHERENTLY DISCLOSED SUBJECT MATTER...continued

2. Hidden Inherent Result

- A hidden inherent result is one that is neither recognizable nor scientifically inferable from what is expressly disclosed and therefore can only be established as fact by empirical evidence.
- A hidden inherent result may be implicitly intended or entirely unintended.

(a) Hidden Inherent Result That is Implicitly Intended

According to this first type of hidden inherent result, the result is a **necessary and inevitable link in the chain of causality** that connects an expressly intended or disclosed action ("cause") to its expressly intended or disclosed result ("effect").

HYPOTHETICAL CASE 2

A chemical process includes the step of reacting X with Y to produce Z. The reaction is later determined to have first produced intermediate Q, Q then undergoing reaction to produce Z.

COMMENT

The production of intermediate Q is not only an inherent result of reacting X with Y, it is also a necessary and inevitable link in the chain of causality connecting the intended action of reacting X with Y ("cause") with the intended production of product Z ("effect"). Although, the production of intermediate Q was not contemporaneously recognized, this inherent result can be considered to have been **implicitly intended** when first achieved since it links the expressly intended cause to its expressly intended effect.

HYPOTHETICAL CASE 3

A patented blow molding machine inherently produces a plastic container with a unique structural characteristic that contributes to its strength. Nowhere in the specification is this structural characteristic disclosed.

COMMENT

The formation of the structural characteristic of the container is not only an inherent result of the normal functioning of the blow molding machine ("cause") to produce the desired container ("effect"), even through this result may not have been appreciated at the time the patent application was filed, it was **implicitly intended** since it links the expressly intended cause to its expressly intended effect.

II. THE CATEGORIES OF INHERENTLY DISCLOSED SUBJECT MATTER...continued

(b) Hidden Inherent Result That is Unintended and Unappreciated – Accidental

Result

According to this second type of hidden inherent result, the result lies **outside the chain of causality** that connects an expressly intended or disclosed action to its expressly intended or disclosed result.

HYPOTHETICAL CASE 4

During the operation of a diesel engine, patented lubricant X degrades over time resulting in the production of non-lubricating chemical compound Y which at first goes undetected.

COMMENT

The production of compound Y is an inherent result since it necessarily and inevitably occurs as the diesel engine accumulates running time. However, the production of compound Y lies **outside the chain of causality** connecting the intended operation of the diesel engine with lubricant X ("cause") and its intended lubrication ("effect") and as such could not be considered as having been intended, implicitly or otherwise. Since the inherent production of compound Y is both unintended and unappreciated, it is an **accidental result**.

II. THE CATEGORIES OF INHERENTLY DISCLOSED SUBJECT MATTER...continued

HYPOTHETICAL CASE 5

Administration of claimed drug compound X to a human subject results in intended therapeutic action Z. An undisclosed but inherent result of the administration of X is the production of metabolite Y which, however, plays no discernible role in achieving or contributing to therapeutic action Z, i.e., Y is an inactive metabolite where therapeutic action Z is concerned.

COMMENT

The production of inactive metabolite Y is **outside the chain of causality** connecting the intended administration of drug compound X ("cause") to its intended therapeutic action Z ("effect") and as such could not be considered to have been an intended result, implicitly or otherwise. The inherent result of the body's production of metabolite Y was not only unrecognized, it was unintended and therefore an **accidental result**.

HYPOTHETICAL CASE 6

A owns a U.S. patent with claims to herbicide compound X, a process for its manufacture and its use as a herbicide. Unknown to A at the time, the claimed process for manufacturing X produces trace amounts of impurity Y having no discernible herbicidal effect.

COMMENT

The production of impurity Y is **outside the chain of causality** connecting the intended process for making X ("cause") with the intended result of producing X ("effect"). The inherent result of producing impurity Y was unrecognized and unintended, even implicitly, and as such must be considered an **accidental result**.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY

A. INHERENT DISCLOSURE AS PRIOR ART

1. Lack of Novelty – the Doctrine of Inherent Anticipation

- According to the doctrine of inherent anticipation, a single prior art publication may anticipate without disclosing a feature of a claimed invention if that **missing feature is necessarily present**, or inherent, in what is expressly disclosed in the publication.
- The **existence of an inherent disclosure** in a prior art reference is a **question of fact**.
- Inherent anticipation requires that the missing feature of a claim be **necessarily present, not merely possibly present**, in the prior art.
- In order for the feature of a claim to be inherent in the prior art, it is not sufficient that someone following the disclosure **sometimes obtain the result** set forth in the claim, the **result must inevitably, or invariably, happen**.
- Inherent anticipation **does not necessarily require that the inherently disclosed subject matter be recognized by those skilled in the art**.
- An inherent disclosure is presumptively enabling barring a showing to the contrary.
- A host document A, e.g., a prior U.S. patent, that properly incorporates by reference subject matter X of another document B, e.g., another U.S. patent, will be treated as a single A/B prior art document and may anticipate a later claim to the A/B subject matter even where the anticipatory subject matter includes inherent disclosure contained in subject matter X of incorporated document B.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY...continued

HYPOTHETICAL CASE 7

In **Hypothetical Case 1**, the prior publication disclosing the process for producing X including its step of recycling a portion of X to the reactor, but not the heat sink function of the recycled product, would be an inherent anticipation of a later claim to the process which recites the heat sink function.

HYPOTHETICAL CASE 8

In **Hypothetical Case 2**, a prior publication disclosing the process for making Z but silent regarding the production of intermediate Q would inherently anticipate a later claim to the process for the production of Q.

HYPOTHETICAL CASE 9

In **Hypothetical Case 3**, the prior patent to the blow molding machine would inherently anticipate a later claim to the plastic container with its unique structural feature inherently produced by the machine.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY...continued

HYPOTHETICAL CASE 10

The main claim of U.S. patent A claims a shoe sole comprising a laminate of a wear-resistant solid polyurethane elastomer outer layer bonded to a porous polyurethane backing layer having certain specified ranges of average pore size and pore volume. Prior U.S. patent B discloses a shoe sole having a wear-resistant solid polyurethane elastomer layer optionally bonded to a porous polyurethane elastomer layer and incorporates by reference U.S. patent C for its disclosure of a porous polyurethane elastomer layer useful for the construction of B's shoe sole. It is later determined that point values of average pore size and pore volume of a porous polyurethane elastomer layer illustrated in a working example of C come within the ranges of values of these properties recited in the main claim of A.

COMMENT

The combined B/C disclosure including the inherent disclosure of incorporated U.S. Patent C anticipates the patented shoe sole.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY...continued

2. OBVIOUSNESS

Recent U.S. case law indicates that inherent disclosure where shown must be considered in connection with the obviousness inquiry.

HYPOTHETICAL CASE 11

Q's U.S. patent A and published priority application B both claim drug compound X and inherently disclose active metabolite Y. Q, aware that he is time-barred by his published priority application B from patenting a "comprising" claim to Y, files a new U.S. application C with claims to "substantially pure Y," "consisting essentially of Y" and "comprising a pharmaceutically acceptable salt of Y."

COMMENT

Although Q's claims to "substantially pure Y", "consisting essentially of Y" and "comprising a pharmaceutically acceptable salt of Y" in application C are novel, Q will need to rebut the presumption of obviousness to which the inherent disclosure of active metabolite Y in his published foreign priority application B gives rise.

HYPOTHETICAL CASE 12

In **Hypothetical Case 10**, point values of average pore size and pore volume that are inherent properties of the porous polyurethane elastomer layer disclosed in the working example of U.S. patent C are close to, but do not lie within, the ranges of these values cited in dependent Claim 2 of U.S. patent A.

COMMENT

The combined B/C disclosure constitutes *prima facie* evidence of the obviousness of the shoe sole of Claim 2 of U.S. patent A.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY...continued

B. INHERENT DISCLOSURE AS SUPPORT FOR THE SUBJECT MATTER OF A CLAIM

- An application may be amended to claim subject matter that is an inherent feature, an inherent result, etc., of what is expressly disclosed without violating the statutory prohibition against the introduction of new matter.
- The inherent feature, inherent result, etc., relied upon as support for a later added claim may be disclosed in a properly incorporated prior publication.
- A reissue application that seeks to broaden the claims of the original patent by adding a claim to inherently disclosed subject matter therein must be filed within two years from the grant of the original patent (35 U.S.C. § 251(d)). Failing this, the inherently disclosed subject matter will be deemed to have been **dedicated to the public**.

HYPOTHETICAL CASE 13

An application claims a novel compound X but assigns to it an erroneous structural formula.

COMMENT

The claim can later be amended to recite the correct structure without introducing new matter. If the claim presenting the erroneous structure has been patented, a reissue application may be filed at any time during the unexpired term of the patent to correct the claim.

HYPOTHETICAL CASE 14

Patent A with a claim to drug compound X inherently discloses active metabolite Y which is responsible for intended therapeutic effect Z.

COMMENT

Unless the patent owner files a broadening reissue application claiming Y within two years from the grant of original patent A, active metabolite Y will have been **dedicated to the public**.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY...continued

C. RELIANCE ON INHERENT ADVANTAGE OR BENEFIT TO REBUT A PRESUMPTION OF OBVIOUSNESS

1. THE INHERENT ADVANTAGE OR BENEFIT IS RELATED TO A DISCLOSED UTILITY

- By disclosing in an application an invention that inherently has an advantage or benefit, applicant necessarily discloses the advantage or benefit even though he says nothing about it.
- An applicant may submit evidence of unexpected results of claimed subject matter based on an inherent advantage or benefit flowing from a disclosed utility.

HYPOTHETICAL CASE 15

A claimed composition X is disclosed to be useful as a protective coating for metals. Composition X is rejected for obviousness over prior art disclosing a similar coating composition Y for the same use. Applicant submits an affidavit presenting experimental results showing claimed composition X to exhibit greater resistance to wear than composition Y, an advantage of composition X nowhere mentioned in the application.

COMMENT

Such affidavit evidence, since it relates to the disclosed use of composition X as a protective coating for metals, must be considered by the examiner as to whether it overcomes the presumption of obviousness.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY...continued

2. THE INHERENT ADVANTAGE OR BENEFIT IS UNRELATED TO A DISCLOSED UTILITY

- A patent need not set forth **all the uses** to which the claimed invention can be put.
- A claimed invention will cover not only the disclosed use(s), but any later-discovered uses(s), benefit(s) and/or advantage(s).
- Where a patent applicant intends to present affidavit evidence of unexpected results of the claimed invention in order to rebut a presumption of obviousness and such evidence is that of an inherent advantage or benefit of the invention flowing from a use unrelated to any disclosed use(s), applicant must first file a continuation-in-part (CIP) application to disclose the new use thereby providing the necessary antecedent basis for the submission of the rebuttal evidence.
- In the case of an issued patent, 35 U.S.C. § 251(a) expressly prohibits the introduction of new matter into a reissue application (as would clearly be the case with a new use for the originally claimed subject matter). The patent owner would therefore be prohibited from disclosing a new use in the reissue application and consequently under current law would be unable to provide the necessary antecedent basis for the submission of unexpected results based on the new use.
- It is not entirely clear from the case law whether the discovery of the new use must stem from an inventor's own work. However, since the inventor is entitled to the benefit of all the uses to which his invention may be put, it should make no difference whether he or someone else discovers the new use serving as the necessary foundation for the submission of affidavit evidence of unexpected results.

III. APPLICATIONS OF THE DOCTRINE OF INHERENCY...continued

HYPOTHETICAL CASE 16

A's U.S. patent application claims drug compound X and its therapeutic use Z. The claims are rejected for obviousness over prior publication P disclosing structurally related drug compound Y for the same therapeutic use. A files a CIP application disclosing and claiming his recently discovered therapeutic use Q for drug compound X, a use that is unrelated to use Z, and submits affidavit evidence showing unexpected results for X compared with Y for new therapeutic use Q.

COMMENT

The patent examiner must consider whether such affidavit evidence of unexpected results overcomes the presumption of obviousness to which publication P gives rise. The examiner may not object to this evidence on the ground that it is based on an unrelated use not disclosed in A's parent application.

HYPOTHETICAL CASE 17

In **Hypothetical Case 16**, instead of being claimed in a patent application, drug compound X is claimed in A's patent involved in an *inter partes* review (IPR) proceeding and currently under reexamination by the USPTO's Central Reexamination Unit (CRU). In response to a rejection for obviousness over prior publication P, A submits an amendment that if entered would amend the patent to disclose new therapeutic use Q thereby establishing the necessary predicate for the submission of affidavit evidence of unexpected results based on new therapeutic use Q.

COMMENT

The CRU will refuse entry of patent owner's amendment since it would result in the introduction of new matter prohibited by 35 U.S.C. § 316(d)(3).

IV. PROOF OF INHERENCY

A. PROOF OF FACTS GENERALLY

- Inherent disclosure is a fact that needs to be proven or disproven, as the case may be, to the satisfaction of the trier of fact, i.e., a patent examiner in the *ex parte* examination of an original, continuing or reissue application, the Central Reexamination Unit (CRU) in the supplemental examination (35 U.S.C. §257), *ex parte* reexamination (35 U.S.C. §§ 302-307), *inter partes* review (35 U.S.C. §§ 311-313) or post-grant review (35 U.S.C. §§ 321-329) of an unexpired U.S. patent, an administrative law judge (ALJ) of the International Trade Commission (ITC) in a patent enforcement proceeding (19 U.S.C. §1337) and, the judge in a bench trial or jury in a jury trial, in a patent infringement action in the federal district court.

1. **Proof** refers to the sum or totality of admissible evidence that is offered to prove or disprove an alleged fact such as that of an inherent disclosure.

2. **Burden of Proof**, in the context of inherency, includes the **Burden of Persuasion**, i.e., the burden that lies with one who would prove or disprove an allegation of inherent disclosure, and the **Burden of Going Forward**, i.e., the burden that lies with one who would refute evidence of an alleged inherent disclosure. The **Burden of Persuasion** remains with the one with whom it initially lies, e.g., the patent examiner/CRU or patent applicant in the USPTO or litigant in the federal district court/ITC whereas the **Burden of Going Forward** can shift from one party to the other during the course of the proceeding/action.

IV. PROOF OF INHERENCY...continued

3. Standard of Proof, in the context of inherency, refers to the level of proof required to prove or disprove an allegation of inherent disclosure.

a. Mere Preponderance of the Evidence simply means that one side has more evidence in its favor than the other, even by the smallest degree. In the USPTO, the mere preponderance standard applies to **all** alleged or disputed facts including those involving inherency.

b. Clear and Convincing Evidence is a standard of proof that lies somewhere between the criminal standard of evidence beyond a reasonable doubt and the mere preponderance standard. In patent litigation within the district courts/ITC, **depending on what needs to be proven**, the lower mere preponderance standard or the higher clear and convincing standard will apply, e.g., the patent owner bears the burden of proving infringement by a mere preponderance of evidence and the accused infringer bears the burden to proving invalidity by clear and convincing evidence.

IV. PROOF OF INHERENCY...continued

B. PROOF OF INHERENCY IN THE FEDERAL COURTS (INCLUSIVE OF THE INTERNATIONAL TRADE COMMISSION)

1. Challenge to Validity of Claim(s) Based on Inherent Disclosure

An accused infringer /challenger of patent claim validity bears the burden of establishing claim invalidity on the ground of inherent anticipation or inherent obviousness as well as any other asserted ground(s) of invalidity by **clear and convincing evidence**. Once the challenger has submitted his proof, the burden shifts to the patent owner to refute challenger's evidence by argument and/or by submission of a **mere preponderance of countervailing evidence**.

2. Reliance Upon Inherent Disclosure as Support for Claim(s)

A patent owner who would rely on inherency to dispute an accused infringer's case for noncompliance with the written description requirement of 35 U.S.C. §112(a) or violation of the prohibition against the introduction of new matter of 35 U.S.C. §132(a) bears the burden of rebutting such case by argument and/or by submission of a **mere preponderance of evidence** demonstrating inherent disclosure of the subject matter of the challenged claim(s) in the specification.

3. Reliance Upon Inherent Advantage or Benefit to Rebut Obviousness

A patent owner bears the burden of rebutting his opponent's case for obviousness by a **mere preponderance of countervailing evidence**, e.g., by submission of at least minimally or marginally persuasive evidence of unexpected results based upon an inherent advantage or benefit of the subject matter of the challenged claim(s).

IV. PROOF OF INHERENCY...continued

C. PROOF OF INHERENCY IN THE USPTO

1. Rejection of Claim(s) Based on Inherent Disclosure

- In rejecting claim(s) on the basis of inherent disclosure in the prior art, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent disclosure necessarily flows from the express teachings of the reference.
- Once the examiner presents evidence or reasoning to show inherency, the burden then shifts to the applicant to refute the examiner's case for inherency by argument and/or by the submission of a **mere preponderance of countervailing evidence**.

2. Reliance Upon Inherent Disclosure as Support for Claim(s)

A patent applicant bears the burden of proving alleged inherent support in his specification for the subject matter of rejected claim(s) by a **mere preponderance of evidence**.

3. Reliance Upon Inherent Advantage or Benefits

Patent applicant bears the burden of rebutting a presumption of obviousness by a **mere preponderance of evidence**, e.g., by submission of at least minimally or marginally persuasive evidence of unexpected results based upon an inherent advantage or benefit of the subject matter of the rejected claim(s).

V. THE DOCTRINE OF ACCIDENTAL RESULT

A. ACCIDENTAL RESULT – OVER 130 YEARS OF JUDGE-MADE LAW

- The doctrine of accidental result functions as a limit on the application of the doctrine of inherent anticipation. In *Tilghman v. Proctor*, 102 U.S. 707 (1880), the United States Supreme Court ruled that " ... If the acids [produced by Tilghman's claimed process] were accidentally and unwittingly produced, whilst the operators [of the prior art devices] were in pursuit of other and different results without exciting attention and without its even being known what was done or how it had been done, it would be absurd to say that this was an anticipation of Tilghman's discovery".
- To this day *Tilghman* remains controlling precedent for the principle that an accidental result, i.e., **an inherent result that is unintended and unappreciated**, cannot provide the basis for a finding of anticipation, or by extension, obviousness.
- The doctrine of accidental result has been invoked in just a few reported decisions to date. Nevertheless, evidence of an inherent result, either as a basis for anticipation, obviousness or support for the subject matter of a claim, warrants further analysis as to whether the result may have been accidental and therefore unavailing as prior art or support for a patent claim.

B. THE ELEMENTS OF AN ACCIDENTAL RESULT

- The elements of an accidental result are threefold:
 - The accidental result must be an inherent result. Should the evidence fail to establish the inherency of a result in the prior art, there can be no possibility of an accidental result and therefore no need to further consider whether the result may have been accidental.
 - The accidental result must not have been intended, even implicitly, at the time it was first achieved.
 - The accidental result must not have been appreciated or recognized, even implicitly, at the time it was first achieved.

V. THE DOCTRINE OF ACCIDENTAL RESULT...continued

HYPOTHETICAL CASE 18

In **Hypothetical Case 4**, non-lubricating compound Y is later identified, synthesized and found to be an effective anti-corrosion agent for metals. A patent later issues with claims to compound Y of "comprising" scope, i.e., a scope that includes Y in any amount and in any mixture of other substances, and its use as an anti-corrosion agent for metals.

COMMENT

Since the earlier inherent production of compound Y resulting from the degradation of lubricant composition X was an accidental result, it cannot serve as an inherent anticipation of the claims of the later-issued patent.

HYPOTHETICAL CASE 19

In **Hypothetical Case 5**, inactive metabolite Y is later identified, synthesized and found to exert a therapeutic effect Q that is totally unrelated to therapeutic action Z. A patent later issues with "comprising" claims to drug compound Y and its therapeutic use Q.

COMMENT

Since inactive metabolite Y was an inherent, but accidental, result of administering drug compound X, it cannot serve as an inherent anticipation of the claims of the later-issued patent.

HYPOTHETICAL CASE 20

In **Hypothetical Case 6**, A's competitor B in the course of evaluating a quantity of A's patented commercial herbicide composition X identifies the presence therein of impurity Y and subsequently discovers that while compound Y exhibits no detectable herbicidal activity, it is effective as a nematocide when used in amounts that are well above the trace amounts that are present in herbicide X. B proceeds to apply for, and obtain, a patent with a claim to Y of "comprising" scope and therefore covering A's commercial herbicide X containing trace amounts of compound Y.

COMMENT

Since the inherent production of impurity Y during the course of producing herbicidal composition X was an accidental result at the time, it cannot serve as an inherent anticipation of the "comprising" claims to Y in B's later-issued patent. However, the possibility that B in these circumstances could successfully sue A for patent infringement based on A's manufacture and sale of composition X exposes a flaw in the oft-repeated maxim "that which would literally infringe it later in time anticipates it earlier", a peculiar state of affairs that has yet to be addressed by the case law.

V. THE DOCTRINE OF ACCIDENTAL RESULT...continued

C. LATER RECOGNITION OF AN ACCIDENTAL RESULT

- Later recognition of an accidental result will not relate back in time such as to make the prior disclosure that embodies the accidental result available as prior art or, as might be expected in the case of a patent application, support for an added claim.
- One who later recognizes and appreciates the potential commercial value of what had until then been an accidental result unknown to the rest of the world has the following options:
 - Maintain knowledge of, but not use or exploit the result, at least for a time.
 - Publish the accidental result whereupon the result becomes prior art as an express disclosure as of the date of publication.
 - Publicly use or commercially exploit the result without drawing attention to it whereupon the result becomes prior art as an inherent disclosure as of the date of first public use or sale.
 - Seek to patent the accidental result.
 - Practice the accidental result as a trade secret.
- In the case of the last-mentioned option, commercial exploitation of the accidental result as a trade secret for more than one year may result in forfeiture of the discoverer's right to later seek a patent to his discovery. However, the discoverer may have a personal defense to infringement in the case of a later-issued patent claiming the subject matter of the accidental result. 35 U.S.C. § 273(a).

V. THE DOCTRINE OF ACCIDENTAL RESULT...continued

D. ACCIDENT RESULT AND INFRINGEMENT

According to the classic test for anticipation/lack of novelty, updated to reflect changes in the law effected by the America Invents Act (AIA), subject matter that would literally infringe if later in time will anticipate if earlier than the effective date of the claimed invention (putting aside the exceptions to prior art in 35 U.S.C. § 102(b)). However, this test does not necessarily hold true where a later-recognized and patented accidental result is concerned. As the following hypothetical cases illustrate, where established principles of the law of infringement encounter the doctrine of accidental result, the outcomes can be quite strange. How a court might deal with any of these unusual, but not far-fetched, scenarios is anyone's guess.

V. THE DOCTRINE OF ACCIDENTAL RESULT...continued

HYPOTHETICAL CASE 21

In **Hypothetical Case 20**, B sues A for patent infringement based on A's continued manufacture and sale of herbicidal composition X containing a trace amount of B's claimed compound Y.

COMMENT

Every act of infringement is actionable even one such as the hypothetical posed here. It would be no defense to B's charge of infringement that A's infringement is of such insignificance that a court might properly choose to disregard it.

An interesting question here is whether A might have a personal defense to B's charge of infringement based on the prior commercial use provisions of 35 U.S.C. § 273. A threshold question in this regard is whether A's prior commercial manufacture and sale of herbicidal composition X could be regarded as the sort of "use" of impurity Y contemplated by the statute when it is considered that impurity Y serves no meaningful use in composition X.

Under the current understanding of the doctrine of accidental result, A cannot rely on the earlier inherent, but accidental, production of compound Y as an anticipation of B's "comprising" claims covering this compound.

What remedies B may be entitled to in this scenario raise additional interesting questions. It would be within the discretion of the court to refuse an injunction against A's continued infringement. And in these circumstances, the court might choose not to approve an award of monetary damage that went beyond a nominal amount.

It is even possible that the trial court, or what is more likely the Federal Circuit were an appeal to be taken by A, might take the occasion of this case to modify the doctrine of accidental result, e.g., by ruling that for a claim to compound Y to be valid and enforceable it could not be of such a scope as to read on composition X. Such a ruling would compel B to seek a narrowing reissue of his original patent, e.g., by replacing its "comprising" claims with claims that avoid literally reading on X.

V. THE DOCTRINE OF ACCIDENTAL RESULT...continued

HYPOTHETICAL 22

In **Hypothetical Case 6**, A later identifies the presence of impurity Y in herbicide composition X and discovering that it is a potent nematocide, applies for and obtains a patent with claims of "comprising" scope to Y and its use as a nematocide. On expiration of A's patent to herbicidal composition X and while A's patent to Y remains in force, A's competitor B starts to manufacture and sell composition X. A sues B for patent infringement based on B's manufacture and sale of a composition containing Y.

COMMENT

This hypothetical illustrates the clash between the doctrine of accidental result as currently understood and the even more fundamental principle that upon expiration of a patent, its claimed subject matter enters the public domain where anyone is free to practice it. Putting aside the improbability that A would seek to enforce his patent to Y against B, it is a virtual certainty that a court would resolve the dilemma posed by this scenario in a way that preserves the public right to practice the subject matter of an expired patent, perhaps by modifying the doctrine of accidental result in the manner suggested above in **Hypothetical Case 21**.

VI. CONCLUSION

In the brief period of time available for the presentation of the doctrine of inherency and the accidental result exception under U.S. patent law, it is possible to no more than touch upon some of their major aspects including the use of hypothetical cases to illustrate the application of these principles in a variety of scenarios. It is hoped that this presentation, brief as it has been, will help to convey a basic understanding of complex topics of U.S. patent law and practice

THANK YOU FOR ATTENDING THIS PRESENTATION