

Does Inherency Have a Place in Determinations of Obviousness?

By DANIEL P. O'BRIEN, PhD, JD, and W. MURRAY SPRUILL, PhD, JD*

IN MAKING A REJECTION based on obviousness under 35 USC §103, a patent examiner considers the prior art references from the perspective of the person of ordinary skill in the art at the time of the invention. The obviousness determination involves a consideration of what the prior art references teach and whether one of skill would combine the prior art teachings to arrive at the claimed invention. Logically, an inherent feature not disclosed in the references or known at the time of the invention seemingly has no place in the obviousness determination.

A fundamental principle of obviousness under 35 USC §103 is that it is predicated on a determination of what is known in the art at the time of invention. On occasion, claims are rejected or invalidated based on assertions of obviousness that depend on the principle of inherency. *Inherency* refers to a determination of whether a characteristic, property, or feature recited in a claim that is not explicitly taught by the prior art, would have necessarily been present in the teachings of the prior art.¹

Inherency primarily applies to anticipation under 35 USC §102. In anticipation analysis, inherency is based on what is necessarily present in the prior art. There is no requirement in anticipation that the skilled artisan would have recognized the inherent element at the time of invention, only that a skilled artisan would recognize at the time of the anticipation inquiry that the inherent element was in fact present. Thus, it would seem to be a contradiction to assert that a claimed invention is obvious because of an inherent and unrecognized property in the prior art given that obviousness cannot be established on the basis of what is not known.²

The law of inherency has become convoluted in and of itself, and many articles have been devoted to the topic of inherent anticipation. Inherency's application to obviousness is even more treacherous because it is easy to fall into the trap of using inherency to reach

claim limitations that are novel by asserting they were inherent in the combined teachings of the prior art. The application of inherency to obviousness will be referred to as *inherent obviousness* for the purposes of this article.

To best frame why inherent obviousness is a problem for both patent practitioners and examiners alike, we provide a hypothetical to illustrate the nuance of the issues.

HYPOTHETICAL

An inventor develops a new biotechnology-based invention that allows the production of a known biomedical polypeptide already used in therapeutic settings. For the purposes of this hypothetical, we will call the polypeptide Protein A. A known issue with the mass production of Protein A was that although mammalian cells express it in culture, proteases in the cells degrade Protein A quickly. Thus, there were many barriers to production requiring the use of protease inhibitors in order to produce enough Protein A for medical use.

The inventor's innovation is the discovery that Protein A can be produced in a plant expression system with little protease degradation of the product. A patent application is filed to cover the production of Protein A in the plant system. This system was known in the art. During examination, the Examiner rejects the claims under 35 USC §103 for obviousness, citing art teaching Protein A in view of art teaching the plant expression system. The Examiner asserts that the skilled artisan would have been motivated to try alternative expression systems, such as the claimed

¹See MPEP §2112.

²*In re Newell*, 891 F.2d 899, 901 (Fed. Cir. 1989), citing *In re Spormann*, 363 F.2d 444, 448 (CCPA 1966) ("Obviousness cannot be predicated on what is unknown"); see also *In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993); MPEP §2141.02(V).

*Alston & Bird LLP, Durham, North Carolina.

system, and that the lack of degradation is an inherent feature of the plant expression system.

In one fell swoop, the Examiner reduces the point of novelty of the invention to an inherent property. Because the case law regarding inherency is rather imprecise, patent practitioners often have trouble discerning a clear path to claim allowance in the face of assertions of inherent obviousness.

Although one must use care in asserting inherent obviousness, it can be used successfully to invalidate or reject a claim. The Patent and Trademark Office provides instructions on the application of inherency to 35 USC §103.³ Further, Federal Circuit precedent suggests instances when it is acceptable practice. Much of the confusion stems from the fact that the authoritative instructions are vague, and not all principles of inherency will work in conjunction with obviousness.

The aim of this paper is to shed light on how to overcome inherency in an obviousness rejection and to propose that an unknown and unpredictable feature or outcome should not be allowed to be used in an obviousness setting. One challenge of our analysis is that the body of case law relied upon for inherency has developed essentially insulated from obviousness. Thus, when inherency is applied to obviousness, the anticipation case law is dropped into the analysis seemingly without thought as to whether it properly fits. To reach the goal of clarifying inherent obviousness, we have reviewed the state of the law with respect to inherency. The key cases the PTO relies on in making inherent obviousness rejections are discussed. We propose that instead of inherency, the court should consider the predictability of a claimed outcome or property. This predictability would be based on the knowledge of one skilled in the art at the time of the invention. The result of our analysis is a framework for determining if a rejection is proper, and a roadmap for traversal if a rejection is improper.

I. CANONICAL INHERENCY

Inherency is applied in anticipation analysis when the examiner cites a prior art reference that discloses almost every claimed element, as required by §102, but is silent on at least one claim limitation. Inherent anticipation of the claim requires that the limitation absent in the teaching of the prior art reference *must* nonetheless be present. That is, an unstated element must exist as a matter of scientific fact and flow naturally from the elements expressly disclosed in the prior art reference.⁴ The burden is on the examiner to provide an explanation as to why the limitation is inherent in the prior art.⁵ The examiner's rationale or evidence must explain why the non-disclosed limitation is necessarily present in the reference. Inherency may not be established by probabilities or possibilities. The fact that a result or characteristic may occur or be present

in the prior art is not sufficient to establish inherency of that result or characteristic.⁶ The overarching policy behind inherency is that if something is already in the public domain, it should not be removed from the public simply due to the recognition of its existence. Therefore, inherency is based on the maxim that "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer."⁷

A commonly cited example of inherency often invoked by the PTO is the case of *Titanium Metals Corp. of Am. v. Banner*.⁸ The issue was whether a claim directed to a titanium alloy containing "0.2–0.4% Mo and 0.6–0.9% Ni, wherein the alloy is resistant to corrosion" was anticipated by a prior art Russian article that disclosed a titanium alloy containing 0.25% Mo and 0.75% Ni but which was silent as to corrosion resistance.⁹ Holding the claim anticipated, the Federal Circuit stated that the claimed property of corrosion resistance was immaterial because it was inherent in the prior art compound.¹⁰ Corrosion resistance was always a property of the alloy, and to allow a patent would remove the free use of the alloy from the public. Therefore, the claims to the composition were anticipated, despite the fact that the property of corrosion resistance was not previously recognized.¹¹

Note that although the burden is on the examiner to provide a reason the inherent feature is present, the

³See MPEP § 2112 ("The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103.").

⁴*Hughes Aircraft Co. v. United States*, 8 U.S.P.Q.2d (BNA) 1580, 1583 (Cl. Ct. 1988).

⁵*Ex parte Levy*, 17 U.S.P.Q.2d (BNA) 1461, 1464 (BPAI 1990) ("In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.").

⁶*In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) ("To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.") (Internal quotes and citations removed.).

⁷*Atlas Powder, Co. v. INRECO, Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

⁸*Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985).

⁹*Id.* at 776.

¹⁰*Id.* at 782.

¹¹*Id.* at 782. ("Congress has not seen fit to permit the patenting of an old alloy, known to others through a printed publication, by one who has discovered its corrosion resistance or other useful properties, or has found out to what extent one can modify the composition of the alloy without losing such properties.").

rationale is not required to provide absolute proof of the inherent feature's presence. Rather, the examiner must make a *prima facie* case.¹² The examiner can support her/his case with a finding of fact or technical reasoning. Once a *prima facie* case has been made, the applicant can then attempt to rebut it.¹³

In anticipation analysis, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention. Therefore, the recognition of the inherent property or feature in the prior art can occur after the filing date of the application. "Simply put, the fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention."¹⁴

It is also of note that the patentability of a claim in the face of inherency can differ depending on whether it is directed to a composition of matter or a method of use. When the claims are based on a structural or functional feature of the invention, and that structure or functional feature is identical or substantially identical to that taught in the prior art, then the claimed properties or functions are presumed to be inherent.¹⁵ Similarly, for compositions of matter, if the composition is physically the same, it necessarily has the same properties; *i.e.*, a chemical composition and its properties are inseparable.¹⁶ However, the discovery of a new use for an old composition based on previously unknown properties of the composition might be patentable as a process of using.¹⁷ A new use must be distinguished from a newly recognized result or outcome of a prior art use of a known compound. The previously unrecognized result of an existing method was already in the public domain and is therefore not patentable.

It is of note that the inherent result of a prophetic example might serve as anticipatory prior art even though the inherent result of the constructive reduction to practice was unrecognized by the scientific community at the time of publication of the prior art. Likewise, anticipation by inherency "requires only an enabling disclosure, not actual creation or reduction to practice."¹⁸ However, "an invitation to investigate is not an inherent disclosure."¹⁹ As noted by the Federal Circuit, "[f]or example, a document that recited administration of all known compounds for treatment of all known diseases, with no evidence that any of these treatments would be effective, would not inherently anticipate all method-of-treatment claims involving those compounds and diseases."²⁰

Two elements are required for a prophetic example to constitute an inherent anticipatory reference: (1) the reference must be enabling; and (2) the result must be predictable. Therefore, in the unpredictable arts, such as biotechnology and methods of disease treatment, the burden of showing inherent anticipation by a prophetic example is high. If a significant amount of experimentation and trial-and-error re-

search would be required to produce the contested invention, then it is arguably not enabled because the result was not predictable.²¹ Undue experimentation is an indication that the inherent result of the prophetic disclosure is a probability or possibility rather than the inevitable result of practicing the disclosed example.

In summary, 35 USC §102 requires that the complete claimed invention be found in a single prior art publication. Inherency allows an examiner to invalidate a claim limitation or an entire claim based on extrinsic evidence that the claimed limitation is found in the reference. There is no requirement that the inherent limitation be recognized by one of skill in the art at the time of invention or filing. For a reference to inherently anticipate a claimed invention, the allegedly inherent characteristic must "*necessarily* [flow] from

¹²See MPEP §2112(IV).

¹³*Id.*

¹⁴*Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1321 (Fed. Cir. 2004).

¹⁵*In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997) (Holding that a cone for dispensing popped corn was inherently anticipated by an oil funnel, the court states, "It is well settled that the recitation of a new intended use for an old product does not make a claim to that old product patentable.")

¹⁶*In re Papesch*, 315 F.2d 381, 391 (CCPA 1963) ("From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing." "And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity of the former compound to the latter.")

¹⁷*Schering Corp.*, 339 F.3d at 1381 (the court held that the metabolite of a known drug was the inherent product of administering the drug and, therefore, anticipated. However, the court stated, "Finally, this court's conclusion on inherent anticipation in this case does not preclude patent protection for metabolites of known drugs. With proper claiming, patent protection is available for metabolites of known drugs.")

¹⁸*In re Montgomery*, 677 F.3d 1375, 1382 (Fed. Cir. 2012), citing *Schering Corp.*, 339 F.3d at 1381, (internal citations omitted); see also *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1343-44 (Fed. Cir. 2005) (holding a chemical patent inherently anticipated and stating that it was irrelevant whether the inherently disclosed chemical was ever actually produced); see also *Elan Pharm., Inc. v. Mayo Found. for Med. Educ.*, 346 F.3d 1051, 1052 (Fed. Cir. 2003) (*en banc*) ("we clarify that invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue experimentation.")

¹⁹*Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004).

²⁰*In re Montgomery*, 677 F.3d at 1383 n. 13.

²¹*Id.* at 1384 (As stated by the dissent, "[a]n invitation to investigate is not an inherent disclosure." This maxim applies *a fortiori* in arts necessitating laboratory research, clinical studies, and other trial-and-error experimentation. In the unpredictable arts, rarely if ever will an untested proposal necessitating further study and optimization meet the stringent inevitability requirement of inherent anticipation.")

the teaching of the applied prior art.”²² In addition, “[i]nherency...may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”²³ The examiner has the initial burden of providing a reasoned argument that the inherent characteristic is found in the prior art. The applicant then has the burden of providing evidence to rebut the examiner’s assertions. Finally, even if a composition is anticipated by a prior art reference, a new method of use may still be patentable.

II. THE APPLICATION OF INHERENCY TO OBVIOUSNESS

The policy underlying the patent law of the United States is to reward innovation and keep that which is in the public domain available to the public. Thus, inherency fits well in the application of anticipation under 35 USC §102 because it prevents previously unrecognized aspects of the prior art from rendering the prior art patentable. However, obviousness is premised on the idea that the claimed invention, while not disclosed in a single prior art reference, is nonetheless obvious and lacking in patentable innovation. The problem we confront is that when inherency is used in obviousness analysis it carries with it all of the meaning associated with inherency as used in anticipation. The introduction of inherency in obviousness creates an apparent conflict with the basic tenet that obviousness is based on what is known in the art at the time of the invention.

A. *The Prima Facie Case*

In any obviousness rejection, the initial burden is on the examiner to put forward a *prima facie* case of obviousness.²⁴ Thus, the examiner must apply the *Graham* factors by: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the pertinent art; and (4) considering objective evidence indicating obviousness or non-obviousness.²⁵ A *prima facie* case of obviousness that relies on inherency requires the examiner to put forth a reasoned explanation within the *Graham* framework as to why the inherent element was present in the prior art based on knowledge available at the time of invention.²⁶ Similar to a rejection under §102, the examiner does not have to prove that the claimed element is inherent in the prior art. A well-supported argument that the element is the inevitable result of a process or is necessarily present in the prior art creates a rebuttable presumption of inherency.²⁷ To rebut the presumption, the applicant must prove that the prior art does not inherently possess the claimed feature.²⁸

The primary issues in inherent obviousness are: (1) whether the inherent feature is known in the art at the

time of invention; (2) whether the inherent feature is needed to provide motivation to combine; (3) whether a reasonable expectation of success requires knowledge of the inherent element; and (4) whether the inherent element was claimed structurally or functionally.

1. Obviousness Cannot Be Premised on What Was Not Known

An obviousness rejection requires the examiner to consider the invention as a whole, including any inherent properties that may be present.²⁹ However, obviousness cannot be predicated on what is not known at the time an invention is made, even if the inherency of a certain feature is later established.³⁰ In *KSR International*, the Supreme Court rejected the rigid application of the teaching, suggestion, or motivation test while acknowledging the importance of identifying “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.”³¹ Importantly, the reasonable expectation of success must be based on the perspective of a person of skill in the art at the time of invention.³² Thus, in cases in which one of the claimed elements is asserted to be inherent in the prior art, and the inherent element was not recognized in the art at the time of invention, then the inherent element cannot also serve as the reason to combine the prior art elements

²²*Ex parte Levy*, 17 USPQ 2d (BNA) at 1464.

²³*In re Robertson*, 169 F.3d at 745.

²⁴See 35 USC §132(a) (“Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application.”).

²⁵*Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966).

²⁶*In re Rijckaert*, 9 F.3d at 1534. *KSR Int’l.*, 550 U.S. at 399 (“While the sequence of these questions might be reordered in any particular case, the factors define the controlling inquiry.”).

²⁷*In re Best*, 562 F.2d 1252, 1254–55 (CCPA 1977) (“where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.”).

²⁸*Id.*

²⁹*In re Papesch*, 315 F.2d at 391 (“From the standpoint of patent law, a compound and all its properties are inseparable.”).

³⁰*In re Rijckaert*, 9 F.3d at 1534; MPEP § 2141.02(V).

³¹550 U.S. at 401.

³²See *Life Techs. Inc. v. Clontech Labs, Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000) (“[r]easonable expectation of success is assessed from the perspective of the person of ordinary skill in the art. That the inventors were ultimately successful is irrelevant to whether one of ordinary skill in the art, at the time the invention was made, would have reasonably expected success.”).

in the way claimed in the new invention.³³ The fact that inherency under 35 USC §102 allows the application of unknown inherent elements without restriction is the most important distinction that can be made from the law of inherency as applied under 35 USC §103.

Despite the distinction between inherent anticipation and inherent obviousness, it is not uncommon for an obviousness rejection to be improperly based on an inherent element that was not recognized in the art at the time of the invention. A potential source of confusion is that when discussing the application of inherency to obviousness in MPEP §2141.02, the MPEP refers to §2112 for the requirements of inherency. As noted *supra*, MPEP §2112 describes inherency as applied under 35 USC §102. Therefore, direction to §2112 may be misleading because, although there is overlap in inherency requirements between 35 USC §102 and 35 USC §103, it is fundamental that obviousness cannot be founded on what was not known. It may also be somewhat confusing because an inherency rejection under 35 USC §102 can seem similar to an obviousness rejection due to the use of extrinsic evidence. However, it is clear that inherency and obviousness are distinct legal concepts.³⁴ Therefore, it is important to distinguish between a feature that is not known in the art at the time of invention and a feature that is merely not discussed by a prior art reference.

2. An Inherent Element Can Support Obviousness When the Element Is Not Disclosed in the Cited Prior Art But Is Nonetheless Known in the Art

In re Best is often cited by the Patent Office for the applicability of inherency to determinations of obviousness and for the principle that a *prima facie* case may be rebutted by the applicant.³⁵ In *Best*, the court was presented with the issue of whether a process claim was obvious over prior art that taught all of the steps of the process of performing a catalysis reaction except the claimed cooling step based on the X-ray diffraction pattern of the resultant product. The court held that the examiner had made a *prima facie* case of anticipation or obviousness, and the applicant failed to rebut the *prima facie* case. Rather than define the cooling step based on rate of cooling as was done in the prior art, the claim defined the cooling step based on the X-ray diffraction pattern of the resultant product. The examiner reasoned that there was no indication that the claimed cooling step was anything more than what would result if heat were simply removed, which was inherent in the prior art.³⁶ The court stated that the applicant only needed to show that for a typical laboratory-scale sample when employed in *the prior art process*, a cooled product with the X-ray diffraction pattern of the disputed claim would not result.³⁷ However, the applicant failed to satisfy this showing and the claims were found to have been both anticipated and obvious.

A caveat of *In re Best* is that the rejection was made under 35 USC §102 and 35 USC §103. Although not

explicitly stated, it appears that the court was applying the principle that anticipation is “the epitome of obviousness,”³⁸ the assumption being that any art that is anticipatory also renders the claimed invention obvious. *In re Best* is best described as a case about inherent anticipation. The prior art taught the claimed method including a cooling step. However, technically, *In re Best* could be applicable to the obviousness rejection, because one of skill in the art would know how to perform the cooling step at the time of invention. Inherency is not required for the obviousness rejection. Inherency is used to reach what was not taught in the reference cited. In obviousness, you can combine a reference and the knowledge of the skilled artisan. Therefore, the obviousness rejection is not based on inherency but on the cited reference in view of the knowledge of a skilled artisan. The tendency of courts to decide cases based on the flawed logic found in

³³*In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981)(“The mere fact that a certain thing may result from a given set of circumstances is not sufficient [to establish inherency.]”(citations omitted)(emphasis added); *In re Spormann*, 363 F.2d at 448 (Holding that an “advantage” cannot be shown by inherency. “That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.”); see *In re Newell*, 891 F.2d 899, 901 (Fed.Cir.1989)(“a retrospective view of inherency is not a substitute for some teaching or suggestion which supports the selection and use of the various elements in a particular claimed combination.”); *In re Rinehart*, 531 F.2d 1048, 1054 (CCPA 1976) (a “reasonable expectation of success” cannot be shown by inherency.); *In re Adams*, 356 F.2d 998, 1002 (CCPA 1966) (The benefit of an invention may be inherent, but that does not mean it is obvious.).

³⁴*W.L. Gore & Assoc. v. Garlock Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983)(pointing out the error of the district court in not applying the *Graham* factors in an obviousness determination, the court states, “apparently [the District Court] assum[ed] that the claimed products, having been found inherent in the processes of Sumitomo and Smith, would have been obvious in view of those references. If so, that was error. Inherency and obviousness are distinct concepts.”)(citing *In re Spormann*, 363 F.2d at 448).

³⁵*In re Best*, 562 F.2d 1252 (CCPA 1977).

³⁶*Id.* at 1254.

³⁷*Id.* at 1255.

³⁸*Id.* at 1255 (citing *In re Skoner*, 517 F.2d 947, 950 (CCPA 1975)(The *Skoner* court held, “Perhaps the rejection should have been founded upon §102 instead of §103. However, this court has sanctioned the practice of nominally basing rejections on §103 when, in fact, the actual ground of rejection is that the claims are anticipated by the prior art. The justification for this sanction is that a lack of novelty in the claimed subject matter, e.g., as evidenced by a complete disclosure of the invention in the prior art, is the ‘ultimate or epitome of obviousness.’ Therefore, we agree with the examiner that the extent of abrasion carried out by Baer et al. can be considered inherently the same as that of appellants. Any other result would permit the allowance of claims drawn to unpatentable subject matter merely through the employment of descriptive language not chosen by the prior art.”) (internal citations omitted).

In re Best has led to a bastardization of inherency and its incorporation into obviousness jurisprudence. It is of note that there is a developing body of case law to suggest that that which is anticipatory is not always obvious.³⁹ This is particularly true when inherency is required to provide the motivation or reasonable expectation of success in combining prior art references.

A case that demonstrates the application of inherency in obviousness without simultaneously basing the rejection on anticipation is *In re Napier*.⁴⁰ The court in *In re Napier* confirmed the rejection of a claim directed to a device for reducing the noise of a gas-powered generator used on airplanes over the combination of a prior art reference disclosing a device for reducing the noise of a jet engine and a prior art reference teaching the underlying scientific principle that was inherently present to make both the claimed and prior art device function.

The invention at issue was directed toward a device for noise reduction on an auxiliary power unit (APU) on an airplane. An APU is a combustion engine that runs while the plane is on the ground to provide power to the plane systems. The noise was reduced by redirecting the noise in a predetermined direction by running a stream of cold air through the exhaust pipe. The cold air is denser than the hot exhaust and results in refraction of the noise. The claims were rejected over a prior art patent involving the propulsion jet engine on an airplane that mixed cold air into the exhaust stream, thereby reducing noise of the jet engine.

Napier argued that the inventions were different because his used “refraction” and the prior art used “mixing.” The court stated, “The inherent teaching of the prior art reference, a question of fact, arises both in the context of anticipation and obviousness.”⁴¹ While the prior art reference used mixing, sound waves are inherently refracted in the prior art system.⁴² Evidence was presented from the *prior art* in the form of a British patent that explicitly stated that sound waves will be refracted from a hot gas to a cold gas due to the difference in densities.⁴³ The court did not find it persuasive that the mechanical source of the sound in the invention (combustion) versus the prior art (propulsion) was different.⁴⁴ The court concluded that it was known in the art that sound waves could be refracted from hot gas to cold gas, resulting in redirection. Therefore, Napier’s apparatus design and the prior art were similar enough that it would have been obvious to one of skill in the art to apply the mechanism already employed in jet engines to internal combustion engines. The court affirmed that “the goal of Johnson, to achieve ‘significant noise reduction’ from aircraft would have motivated one of skill in the art to apply teachings regarding noise reduction methods applicable to shear-generated noise from an aircraft’s propulsion engine to the parallel problem of combustion noise from an aircraft’s non-propulsion APU.”⁴⁵

Thus, although there was enough difference in the prior art references to foreclose anticipation, the court reasoned that one of skill in the art would have been motivated to utilize the prior art designs and principles to solve the analogous problem presented by a different engine design. Even though the inventor’s application and prior art defined the mechanism differently, one of skill in the art would have had a reasonable expectation of success in reaching Napier’s claimed invention because the inherent principle underlying the inventions was the same and was recognized as predictable in the prior art.

3. An Unrecognized Inherent Property Cannot Be Necessary to the Foundation of a Reasonable Expectation of Success

In contrast to *In re Best* and *In re Napier*, *Ex parte Novitski* demonstrates that an invention can be anticipated by the prior art while being found nonobvious, thereby making it a good example of the major distinction between a §102 inherency analysis and a §103 analysis.⁴⁶ Novitski’s claims were directed toward a method of immunizing plants against nematodes using a particular *Pseudomonas* strain. The examiner made an obviousness rejection based on a primary reference showing the use of the *Pseudomonas* strain on plant roots. The examiner stated that (1) the prior art reference did not expressly disclose that the bacterial strains of *Pseudomonas cepacia* type Wisconsin possess nematode-inhibiting activity; and (2) the reference did not expressly disclose a method for protecting a plant from plant pathogenic nematodes. The examiner attempted to make up for the deficiencies of the primary reference by citing art showing methods of testing bacteria for nematode-inhibiting properties.

³⁹*Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1364 (Fed. Cir. 2008) (“While it is commonly understood that prior art references that anticipate a claim will usually render that claim obvious, it is not necessarily true that a verdict of nonobviousness forecloses anticipation. The tests for anticipation and obviousness are different. Obviousness can be proven by combining existing prior art references, while anticipation requires all elements of a claim to be disclosed within a single reference. Moreover, obviousness requires analysis of secondary considerations of nonobviousness, while secondary considerations are not an element of a claim of anticipation. And although anticipation can be proven inherently, proof of inherent anticipation is not the same as proof of obviousness. Thus, ‘it does not follow that every technically anticipated invention would also have been obvious.’”) (internal citations omitted).

⁴⁰55 F.3d 610 (Fed. Cir. 1995).

⁴¹*Id.* at 613.

⁴²*Id.*

⁴³*Id.*

⁴⁴*Id.* at 614.

⁴⁵*Id.*

⁴⁶*Ex parte Novitski*, 26 USPQ 2d (BNA) 1389 (BPAI 1993).

The Board held that the secondary references relied on by the examiner did not teach or suggest that the primary prior art reference's bacterial strains of *Pseudomonas cepacia* type Wisconsin may reasonably be expected to possess nematode-inhibiting activity.⁴⁷ "The secondary references relate to screening bacteria for nematode-inhibiting activity and, at the most, attribute such activity to several strains of *Pseudomonas* bacteria which are not *Pseudomonas cepacia*."⁴⁸ The Board ruled that the examiner had not made a *prima facie* case because the person of skill in the art would not have a reasonable expectation of success based on the art cited by the examiner.⁴⁹ However, the board entered a new ground for rejection under §102 because the method taught by the primary prior art anticipated the claimed method. The nematode-inhibiting properties of the bacteria were inherent to the strain used in the primary prior art.⁵⁰ The Board's decision illustrates that an obviousness determination cannot be premised on what is not known in the art, while, as discussed *supra*, an anticipation rejection does not require knowledge of an inherent property in the prior art.

Similarly, in *Amgen, Inc. v. F. Hoffmann-LaRoche Ltd.*, the Federal Circuit found that claims directed toward methods of generating and isolating glycosylated erythropoietin (EPO) in cell culture were not obvious in view of a prior invention directed to CHO cells transfected with EPO.⁵¹ One of the elements on appeal was whether claim 27 of Amgen's '008 patent invalidated claims 1 and 2 of Amgen's '868 patent and claims 6–9 of Amgen's '698 patent through obviousness-type double patenting.⁵² The invention at issue was the basis for two erythropoiesis-stimulating agent drugs. Claim 27 of the '008 patent was directed to a "CHO cell capable of glycosylating EPO-transfected with a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of EPO to allow possession of the stated biological properties."⁵³ Claims 1 and 2 of the '868 patent covered a process of "producing EPO that involves (a) growing mammalian cells (CHO in claim 2) transfected with DNA encoding EPO and (b) isolating from those cells glycosylated EPO having the stated biological properties *in vivo*."⁵⁴

In its obviousness analysis, the court does not specifically state that inherency is applied. However, the arguments put forward in favor of obviousness is that the limitations of claims 1 and 2 requiring glycosylated EPO having *in vivo* functionality would be present; *i.e.*, inherent, in claim 27 because it is the inevitable result of transfecting CHO cells with EPO DNA.⁵⁵ It is of note that claim 27 did not require that the EPO actually be glycosylated, only that it was capable of being so.⁵⁶ The court rejected the argument that transfected CHO cells would inevitably express glycosylated EPO, instead relying on testimony from an Amgen scientist that at the time of invention, the early-mid 1980s, there would not have been a reasonable expectation of success because

it was not known if CHO cells would glycosylate the protein properly.⁵⁷ Furthermore, at the time, no one had expressed glycosylated proteins in mammalian cell culture.

Amgen demonstrates in a biotechnology setting that even if the inherent aspect of the invention is an inevitable result, if there is not a reasonable expectation of success at the time of invention, then the claimed property is not obvious. This is because without knowledge, the result is only a mere possibility or probability rather than inevitable. The court states, "We conclude...that a person of ordinary skill in the art would not have reasonably expected to successfully isolate from transfected CHO cells recombinant EPO glycoprotein having the stated biological activities."⁵⁸ The court also stresses that it must be the skilled person's reasonable expectation of success, not the inventor's expectation of success.⁵⁹ Furthermore, the court points out that expert testimony presented observing that the transfected CHO cells recited in claim 27 do produce glycosylated EPO having the stated biological activity is one of hindsight, not of reasonable expectation of success at the time of the invention.⁶⁰

B. Exceptions to the Rule

Despite the fact that obviousness cannot be predicated on what was not known at the time of invention, exceptions exist that allow the application of inherency even though the inherent property was not recognized by those in the art at the time of the invention. Such exceptions arise in two narrow factual scenarios. The first allows the application of inherency to a claimed composition for a particular use where a

⁴⁷*Id.* at 1390.

⁴⁸*Id.*

⁴⁹*Id.*

⁵⁰*Id.* at 1390–91.

⁵¹*Amgen, Inc. v. F. Hoffmann-LaRoche Ltd.*, 580 F.3d 1340 (Fed. Cir. 2009).

⁵²*Id.* at 1361 (An obviousness type double patenting rejection is analogous to a failure to meet the non-obviousness requirements of §103, except that the patent principally underlying the double patenting rejection is not considered prior art. All three patents had the same specification. However, the '698 and '868 patents did not get the protection afforded divisional patents because they were filed as continuation rather than divisional applications.).

⁵³*Id.* at 1358.

⁵⁴*Id.* at 1359 (Claims 6–9 of the '698 patent were similar to claims 1 and 2 of the '868 patent but with an additional limitation that the host cells comprise DNA, which includes a marker gene in claim 7 that is DHFR in Claim 8.).

⁵⁵*Id.* at 1360.

⁵⁶*Id.* at 1362.

⁵⁷*Id.* at 1362–63.

⁵⁸*Id.* at 1363.

⁵⁹*Id.*

⁶⁰*Id.*

substantially similar composition is found in the art. The second exception allows invalidation of a claim limitation when the claimed element was inherently present in the prior art and not required to provide motivation or a reasonable expectation of success in arriving at the claimed invention. Examples are provided in the following sections.

1. The *Dillon* Exception

An exception to the traditional *prima facie* case can be found in *In re Dillon*,⁶¹ a case often cited by the Patent Office that stands for the principle that the motivation to combine the prior art does not have to match the inventor's motivation. This allows the examiner, under a limited factual situation, to circumvent the fact that the person of skill in the art is not aware of the inherent property in the prior art that is taught by the inventor's patent application.

In *In re Dillon*, an *in banc* court held that when the prior art functions the same as the claimed composition and the claimed composition only differs by interchangeable equivalents, then the claimed composition is obvious.⁶² The claim at issue was directed to a composition comprising a hydrocarbon fuel and a sufficient amount of a tetra-orthoester to reduce the particulate emissions from combustion. Tetra-orthoesters were known compounds. However, their use in fuel was not known in the prior art. The examiner cited prior art showing the use of chemically similar tri-orthoesters in fuel as a co-solvent to prevent phase separation between fuel and alcohol. The examiner then cited an additional reference teaching the use of tri- and tetra-orthoesters in a similar type of chemical reaction and a reference teaching the orthoesters as equivalents for a particular practical use.⁶³ The court agreed that the art teaching the orthoesters as functional equivalents combined with the use of tri-orthoesters in the fuel arts was sufficient to create a *prima facie* presumption of obviousness because the tri-orthoester-containing fuel would function as an equivalent for tetra-orthoester.⁶⁴ Although *Dillon*'s claimed composition was not previously known, fuel containing tri-orthoesters was known, and one of skill in the chemical/fuel art would have recognized the interchangeability of the orthoesters.

Significantly, the court indicated that the motivation to combine the prior art was not required to match the inventor's motivation, nor did the expectation of success.⁶⁵ Thus, the motivation to use tetra-orthoester in fuel does not have to be for emission reduction. It was acceptable that the motivation presented by the examiner was to use tetra-orthoester as a co-solvent in the fuel similar to tri-orthoesters with the inherent, unrecognized effect of also reducing emissions because tri- and tetra-orthoesters would both presumably reduce emissions. "Properties must be considered in the overall evaluation of obviousness, and the lack of any disclosure of useful properties for a

prior art compound may indicate a lack of motivation to make related compounds, and thereby preclude a *prima facie* case, but it is not correct that similarity of structure and a suggestion of the activity of an applicant's compounds in the prior art are necessary before a *prima facie* case is established."⁶⁶

It is of note that the claimed compound and the prior art differed only by orthoester content, and it was known at the time of invention that tetra- and tri-orthoesters were functional equivalents for at least one purpose. Therefore, the examiner had created a rebuttable presumption of obviousness. To find that the prior art provides a reason or motivation to make the claimed composition when the reason is different than the inventor's likely requires that the prior art composition and the claimed composition be almost identical.

Unlike a rejection for anticipation, it would not be acceptable to show that after the date of invention it became known in the art that tetra-orthoester had the equivalent function of tri-orthoester, because obviousness cannot be predicated on what was not known at the time of invention.⁶⁷ Therefore, if tetra-orthoesters had not been known to have similar chemical properties to tri-orthoesters at the time of invention, then *Dillon*'s composition would not have been obvious even if the orthoesters were found post-invention to have functioned equivalently to reduce emissions.

In re Dillon appears to be a narrow holding, as demonstrated by *Rhône-Poulenc Agro, S.A. v. DeKalb Genetics Corp.*⁶⁸ DeKalb asserted that Rhône-Poulenc's patent was obvious as an affirmative defense to infringement. The patent at issue claimed a Roundup Ready[®] Corn. The corn transgenically expressed an EPSPS (5-enolpyruvyl-3-phosphoshikimate synthase) enzyme of *Salmonella* origin that imparted tolerance to the active ingredient in Roundup, glyphosate.⁶⁹ Glyphosate tolerance required

⁶¹*In re Dillon*, 919 F.2d 688 (Fed. Cir. 1990)(*en banc*).

⁶²*Id.* at 692.

⁶³*Id.*

⁶⁴*Id.*

⁶⁵*Id.* at 693.

⁶⁶*Id.* at 698.

⁶⁷*In re Newell*, 891 F.2d 899 (Fed. Cir. 1989); *In re Rijckaert*, 9 F.2d 1531 (Fed. Cir. 1993).

⁶⁸272 F.3d 1335 (Fed. Cir. 2002).

⁶⁹*Id.* at 1341 ("The C-aroA gene is an 'EPSPS' gene derived from a *Salmonella* bacterium. Inside a plant, the herbicide glyphosate binds to a specific enzyme in a plant chloroplast, called EPSPS (5-enolpyruvyl-3-phosphoshikimate synthase enzyme), which then cannot perform its normal critical function in the biosynthesis of aromatic acids, and the plant dies. When the C-aroA gene is expressed in transgenic plants, the bacterial EPSPS enzyme encoded by this gene fulfills the aromatic amino acid needs of the plant in the presence of glyphosate, whereas the plant version of this enzyme (ubiquitous in nature) is sensitive to glyphosate.").

that EPSPS localize to the chloroplast of the corn plant. The claim at issue was directed to a nucleic acid sequence that encoded an EPSPS with two N-terminal chloroplast transit peptide sequences.⁷⁰ The closest prior art taught the same enzyme with only one N-terminal chloroplast transit sequence.

Citing *In re Dillon*, DeKalb argued that the prior art publication alone rendered the claim obvious, asserting that “the structural variation between the two, *i.e.*, the second transit peptide, is an irrelevant variation, and therefore the claim is obvious.”⁷¹ The court said that to draw the *Dillon* analogy, “DeKalb must demonstrate that in the relevant field of art, plant molecular biology, it was expected that constructs imparting glyphosate tolerance would have similar properties with and without a second transit peptide.”⁷² Two factors went against DeKalb: (1) DeKalb did not point to evidence that demonstrates any expectation in the relevant field of art regarding the effect of a second transit peptide on glyphosate tolerance constructs (or any constructs); and (2) substantial evidence was presented at trial demonstrating that the second transit peptide, far from being a “useless structural variation” as claimed by DeKalb, serves an important purpose.⁷³ The first factor demonstrates that at the time of invention, it was not known in the art whether a second transit peptide would affect intracellular localization. Therefore, even though the invention comprised the prior art sequence and only added an identical, second N-terminal targeting sequence, the invention was not obvious because there was a beneficial effect of the second N-terminal targeting sequence that was not known at the time of the invention. The second factor demonstrates that even if DeKalb had succeeded in making a *prima facie* case, Rhône-Poulenc submitted sufficient post-filing rebuttal evidence that the second transit peptide did provide a functional advantage over the prior art. Therefore, the claim was held to be non-obvious.

2. *In re Kubin*

Another exception in which an unknown, inherent feature can invalidate a claim limitation as obvious is when the limitation is claimed functionally, rather than structurally, and knowledge of the functional limitation is not required to combine references. In *In re Kubin*, the Federal Circuit decided a case of obviousness based in part upon an inherent element that was claimed functionally.⁷⁴ The BPAI had found obvious claims drawn to DNA molecules encoding a protein known as natural killer cell activation-inducing ligand (NAIL). The claim recited: “An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22-221 of SEQ ID NO:2, wherein the polypeptide binds CD48.”⁷⁵ The cited primary prior art reference was a patent disclosing the p38 protein (NAIL) and an

anti-p38 monoclonal antibody (mAb). The secondary reference was a molecular cloning protocol manual that delineated methods for determining DNA sequences from amino acid sequences.⁷⁶ The court affirmed the BPAI ruling that conventional molecular cloning techniques could have been used to isolate and sequence p38 using the mAb and that the DNA sequence could readily have been determined.

With regard to inherency, there was no explicit teaching in the prior art to show that p38 binds CD48 as required by the claim. However, the court stated that the CD48 binding property was necessarily present in the p38 structure.⁷⁷ Despite the fact that the CD48 binding property was unknown at the time of invention, the application of inherency to obviousness in this situation was appropriate because the knowledge that p38 binds CD48 would not be required for the motivation to isolate a p38 nucleic acid sequence, or for a reasonable expectation of success at the time of invention.⁷⁸ This is because one could clone the DNA sequence for p38, and thereby reach the claimed invention, without knowledge that p38 can bind CD48. Essentially, because the polypeptide was structurally described, the function of binding CD48 added no further patentable limitations.

⁷⁰*Id.* at 1357 (The claim was directed to a nucleic acid sequence that encodes a fusion polypeptide comprising a first chloroplast transit peptide from a sunflower ribulose-1,5-bisphosphate carboxylase small subunit, approximately 22 amino acids from the N-terminal region of a mature maize ribulose-1,5-bisphosphate carboxylate small subunit and a second chloroplast transit peptide from a maize ribulose-1,5-bisphosphate carboxylate small subunit.).

⁷¹*Id.*

⁷²*Id.*

⁷³*Id.*

⁷⁴*In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

⁷⁵*Id.* at 1353 (emphasis added) (“In other words, appellants claim a genus of isolated polynucleotides encoding a protein that binds CD48 and is at least 80% identical to amino acids 22–221 of SEQ ID NO:2—the disclosed amino acid sequence for the CD48-binding region of NAIL.”).

⁷⁶*Id.* at 1356.

⁷⁷*Id.* at 1357 (“It is not invention to perceive that the product which others had discovered had qualities they failed to detect.”), citing *Gen. Elec. Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 249 (1945) (“[A] structure suggested by the prior art, and, hence, potentially in the possession of the public, is [not] patentable...because it also possesses an inherent, but hitherto unknown, function which patentees claim to have discovered”); also citing *In re Wiseman*, 596 F.2d 1019, 1023 (CCPA 1979).

⁷⁸*Id.* at 1360 (The court notes that “[m]oreover, the record strongly reinforces (and appellants apparently find no room to dispute) the Board’s factual finding that one of ordinary skill would have been motivated to isolate NAIL cDNA, given Valiante’s teaching that p38 is ‘expressed by virtually all human NK cells and thus plays a role in the immune response.’”).

III. TRAVERSING AN OBVIOUSNESS REJECTION THAT RELIES ON INHERENCY

In summary, in asserting a case based on inherent obviousness, the examiner must make a *prima facie* case based on the *Graham* factors. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references, when combined) must teach or suggest all the claim limitations.⁷⁹ The examiner cannot rely on an inherent element as the reason to combine references or as the basis for the reasonable expectation of success. Use of an inherent element that was not known is actually impermissible hindsight in which the examiner has used knowledge gleaned only from the applicant's disclosure. However, exceptions exist.

The first exception is exemplified by *In re Dillon*. If a prior art teaching is almost identical to the claimed invention, the point of novelty in the invention is a component that is known in the art, and a known functional equivalent for the point of novelty is found in the same prior art teaching, then an examiner may assert a *prima facie* case of obviousness based on the assertion that the prior art inherently functions the same as the claimed invention. The assertion that the prior art component and the claimed component share an identical function or property must be based on knowledge that was known at the time of invention and supported by more than mere conclusory statements. The motivation to combine is not the inventor's motivation to reach the novel composition, but rather motivation to make a composition with the same function as the prior art composition. The applicant may then rebut the presumption created by the *prima facie* case by showing that the claimed invention and the prior art possess different properties or functions.

The second exception is applicable when motivation exists to combine the prior art references even in the absence of knowledge of the inherent element, so long as one of skill would recognize that the inherent element is the inevitable result of the combination. This means that the inherent element cannot be the reason to combine. There must be a reasonable expectation of success without knowledge of the inherent element. If the examiner is applying principles or teachings that can only be found in the specification of the application to assert that the inherent element is the inevitable result, then the *prima facie* case is improper.

To see these principles in action, we return to the hypothetical from the beginning of our discussion, drawn to an invention for producing Protein A using a plant expression system. The advantage of the system is that Protein A is not degraded in the plant cul-

ture system of the invention. The examiner has rejected the claims as obvious asserting that Protein A was known, the plant expression system was known, and the lack of degradation is merely an inherent feature of expressing Protein A in the known system.

One of the significant stumbling blocks in rebutting a rejection such as the one present in our hypothetical is that the lack of proteases that degrade Protein A is *technically inherent* in the plant expression system. There is no question that the plant cells in the expression system do not express the class of proteases that degrades Protein A. Even though this fact is newly discovered, the plant cells never expressed the protease even before the inventor attempted to express Protein A.

To rebut an obviousness rejection where the examiner is relying on inherency, the applicant should attempt to cast doubt on the predictability of the necessary result by pointing to flaws in the technical arguments. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. The applicant should be on the lookout for conclusory arguments based on applicant's own specification. Unless one of skill in the art could predict the outcome at the time of the invention, the rejection fails. To overcome the rejection, one should demonstrate that the examiner's asserted inherent outcome is a mere possibility based on the knowledge of the skilled artisan at the time of invention.

The applicant should be able to overcome the *prima facie* case of obviousness by using the following arguments:

- There are many expression systems, and they are not readily interchangeable;
- The fact that Protein A can be made in the plant expression system is an unexpected result that could not be predicted at the time of the invention;
- It was not known that the plant expression system did not possess the proteases that led to Protein A degradation.

Asserting that the system possesses the inherent characteristic is impermissible hindsight.⁸⁰ The skilled artisan would not have been motivated to use the plant expression system because the skilled artisan would not have known that the plants lacked the pertinent proteases.

⁷⁹See *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

⁸⁰MPEP §707.07(f), Form Paragraph 7.37.03, "In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392 (C.C.P.A. 1971)" (emphasis added).

An examiner could respond in the next office action that one of skill in the art would have been motivated to try the plant expression system because mammalian expression systems provide suboptimal results. The examiner could assert that the skilled artisan would have screened potential expression systems and would have arrived at the known plant expression system of the claimed invention. Thus, the motivation of the skilled artisan was not based on knowledge of the inherent characteristic, but rather it was based on the skilled artisan's motivation to search for an expression system that did not degrade Protein A.

The counterpoint to this argument is that there were many potential expression systems at the time of the invention. Any number of bacterial, yeast, insect, plant, etc. systems were known. Any cell line was a potential expression system. Therefore, the assertion that it would have been obvious to try is invalid because the solution was not one of a finite number of potential solutions available in the art. It was more akin to throwing darts at the metaphorical dartboard and hoping to find the expression system that works. The Federal Circuit has held that the latter scenario does not qualify as proper motivation or obvious to try.⁸¹ Therefore, the examiner should be persuaded by attorney argument that the invention is not rendered obvious simply because the hypothetical skilled artisan would laboriously screen many expression systems in search of one that does not degrade Protein A.

In the hypothetical, it could be also argued that there was not a reasonable expectation of success because plants are known to express numerous proteases and there was no guarantee that those proteases would not degrade Protein A. The examiner's rationale is essentially that there was a reasonable expectation of success because the plants would inherently not degrade Protein A. However, without knowledge in the art at the time of invention that the plant cells did not express the offending protease, there is no basis for such a conclusory argument.

In our hypothetical, rather than being an inherent characteristic, the lack of Protein A degradation is an unexpected result. Unexpected results are a secondary consideration of non-obviousness that the examiner must consider as evidence in rebuttal of a *prima facie* case. Every one of the expression systems tested in the prior art has Protein A stability issues. Not only does the plant expression system express functional Protein A, it unexpectedly lacks the degradation issues found in other expression systems. One of skill in the art at the time of the invention would not have had a reasonable expectation of success in using the plant expression system, because plants express many proteases that could have potentially degraded Protein A. Thus, given the many difficulties and failure of others to express Protein A in a stable expression system, the successful expression in the plant expression system was indeed unexpected. Therefore, the skilled artisan lacked motivation and a reasonable expectation of suc-

cess and the examiner could not rely on an unknown result in making the obviousness rejection.

IV. CONCLUSION

Inherency is one of the most confusing doctrines in patent law. It has confounded examiners, practitioners, inventors, and judges. As exclaimed by one judge in a case ultimately decided using inherent anticipation, "This is heady stuff; someone not steeped in patent law might think it loony..."⁸² In our opinion, using the term *inherency* in an obviousness analysis confounds an already confusing doctrine.

Inherency is a term of art in patent law that has taken on a specific meaning in an anticipation analysis. In such an analysis, inherency is used to supply a claimed outcome or element that is necessarily present, but not known. Essentially, if one is claiming a method or a composition that is already in the public, the addition of an unknown benefit or property into the claim cannot make the old method or composition patentable. The benefit or property is inherent in the practice of the method or use of the composition. It is the unknown—yet necessarily present—aspect of inherency that causes problems in an obviousness setting.

In an anticipation analysis, one can logically follow that if a method has been practiced in the past, a newly discovered outcome of the same method must have been present in the prior art. This newly discovered outcome cannot make the old method novel. The applicant has just discovered an unknown benefit. The inherency principle operates to prevent the patenting of a method or outcome that was already enjoyed by the public due to the fact that "inherency places subject matter in the public domain as well as an express disclosure...."⁸³ Whether recognized or not, the inherent benefit was there by virtue of the identical method.

⁸¹*In re Kubin*, 561 F.3d at 1359, citing *KSR*, 550 U.S. at 421 ("In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is succinctly encapsulated by the Supreme Court's statement in *KSR* that where a skilled artisan merely pursues 'known options' from a 'finite number of identified, predictable solutions,' obviousness under §103 arises.").

⁸²*SmithKline Beecham Corp. v. Apotex Corp.*, 247 F. Supp. 2d 1011, 1027 (N.D. Ill. 2003)(discussing inherent anticipation), cited by Todd Miller, Patented Compounds Inherently Coproduced as Trace Impurities: Issues of Inherent Anticipation and Literal Infringement, 32 AIPLA Q.J. 425 (2004).

⁸³*Schering Corp.*, 339 F.3d at 1379 ("Because inherency places subject matter in the public domain as well as an express disclosure, the inherent disclosure of the entire claimed subject matter anticipates as well as inherent disclosure of a single feature of the claimed subject matter.").

In contrast, in an obviousness rejection, no single reference teaches the claimed invention. Accordingly, there has been no prior art practice of the claimed method or use of the claimed composition. As we have stressed, obviousness relies on what a person of ordinary skill in the art would be led to do, and is based on what is known at the time of the invention. Thus, an examiner cannot use an unknown element or outcome to provide motivation to combine the references, or to provide an expectation of success. Yet, when we speak of inherency in an obviousness determination, it implies that the determination is based on what was unknown at the time of the invention. Accordingly, the use of inherency in obviousness results in an apparent conflict with the basic tenets of patent law.

In the case law, where inherency has been used in obviousness, the inherent aspect was predictable based on the knowledge of one of skill in the art at the time of the invention. The underlying principle was known to one of skill in the art. In *Kubin*, for example, the inherent element would have been a predictable aspect of the claim at the time of the invention. The *Kubin* court upheld the rejection of the claims as obvious over the prior art references, Valiante and Sambrook. The Valiante reference taught the receptor protein, a monoclonal antibody specific for the protein, and that the protein sequences for the receptor could be obtained by conventional methodologies known to one of skill in the art.⁸⁴ Sambrook was cited as teaching such conventional methodologies.⁸⁵ The claims were drawn to nucleic acid molecules encoding polypeptides and polypeptides that were at least 80% identical to amino acids 22–221 of SEQ ID NO:2, wherein the polypeptide binds CD48.⁸⁶ In claims having percent identity language, a functional limitation is required to define the group of sequences covered by the claim. The limitation is not relied on to provide novelty for the claimed sequences. Hence, the function lends no patentable weight to the claims, except for the 35 USC §112 analysis.⁸⁷ Because the court did not address the written description rejection of the claims, the limitation need not have been considered.⁸⁸

In finding the claims obvious, the court addressed this binding limitation and stated that “the Board had no obligation to predicate its obviousness finding on factual findings regarding a prior art teaching of NAIL’s binding to the CD48 protein.”⁸⁹ The court discussed that the CD48 binding is not an additional requirement imposed by the claims, but rather a property necessarily present in NAIL. The court then relied on *In re Wiseman* to conclude that an inherent—but unknown—function, which patentees claim to have discovered, is not necessarily patentable.⁹⁰

The reliance on inherency as an unknown, but necessarily present, element was not needed to confirm that the claims were unpatentable. The combination of the teachings of Valiante and Sambrook would result in obtaining the receptor sequence, amino acids 22–221

of SEQ ID NO:2. That fact, in itself, should have been enough to render the claims obvious.⁹¹ Should the court have wished to address the binding limitation, it would have been sufficient to note that one of skill in the art at the time of the invention would have predicted that two identical proteins would have the same properties, including binding properties. That would have addressed the issue without introducing the confusing inherency argument into the rejection.

In *Dillon*, although the examiner and the Board relied on inherency to find the claims obvious, the court did not mention inherency in the majority opinion. In *Dillon*, the examiner made a *prima facie* case of obviousness over the claimed composition because the chemical used in the prior art was known to be interchangeable with the claimed chemical.⁹² To overcome the rejection, Dillon argued that the composition was designed for a new use.⁹³ Although the examiner and the Board argued that Dillon merely recited a newly discovered function inherently possessed by the prior art, the majority opinion noted that the claims are drawn to compositions and that the PTO provided the motivation to make such new compositions.⁹⁴ The court noted the structural similarity between the

⁸⁴*In re Kubin*, 561 F.3d at 1354.

⁸⁵*Id.*

⁸⁶*Id.* at 1353.

⁸⁷*Id.* at 1353 (regarding written description, the court states, “the Board observed that although appellants had sequenced two nucleic acids falling within the scope of claim 73, they had not disclosed any variant species where amino acids 22–221 were different in any way from the disclosed SEQ ID NO:2 sequence. Thus, the Board concluded that appellants were not entitled to their genus claim of DNA molecules encoding proteins 80% identical to SEQ ID NO:2. ...”).

⁸⁸*Id.* at 1361.

⁸⁹*Id.* at 1357.

⁹⁰*Id.* at 1357–58, citing *In re Wiseman*, 596 F.2d at 1023 (stating that the *Wiseman* court rejected “the notion that ‘a structure suggested by the prior art, and, hence, potentially in the possession of the public, is patentable...because it also possesses an inherent, but hitherto unknown, function which [patentees] claim to have discovered. This is not the law. A patent on such a structure would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art.’”).

⁹¹*Id.* at 1357.

⁹²*In re Dillon*, 919 F.2d at 692.

⁹³*Id.*

⁹⁴*Id.* (“We believe that the PTO has established, through its combination of references, that there is a sufficiently close relationship between the tri-orthoesters and tetra-orthoesters (see the cited Elliott and Howk references) in the fuel oil art to create an expectation that hydrocarbon fuel compositions containing the tetra-esters would have similar properties, including water scavenging, to like compositions containing the tri-esters, and to provide the motivation to make such new compositions. Howk teaches use of both tri- and tetra-orthoesters in a similar type of chemical reaction. Elliott teaches their equivalence for a particular practical use.”).

claimed and prior art compositions and pointed out that the discovery of a new property does not by itself defeat a *prima facie* case.⁹⁵

Dillon argued that the Board did not consider the unexpected results produced by her invention.⁹⁶ The court agreed with the Board that no unexpected results had been shown for the claimed compositions compared with the prior art compositions.⁹⁷ Thus, instead of relying on inherency, the court indicated that the claimed compositions were obvious in view of the cited art, and applicant had not met her burden of showing unexpected results. To rephrase the outcome using our predictability analysis, because the claimed composition and the prior art composition are substantially the same, one of skill in the art would predict that the prior art composition would have the same properties as the claimed composition. The burden was on Dillon to prove otherwise.

Many of the inherent obviousness cases cite to *In re Wiseman*.⁹⁸ In *Wiseman*, the issue confronted by the court was whether an airplane brake system that comprised a carbon disc system that utilized grooves to dissipate steam caused by heat from the braking action was obvious.⁹⁹ The court held that the system was obvious because a prior art reference taught a carbon disc braking system useful in aircraft applications and a separate reference taught the use of grooves to dissipate dust generated from braking action in an automotive brake assembly. The court reasoned that one of skill in the art would have been motivated to combine the references to dissipate dust in the carbon disc system.¹⁰⁰ The appellants argued that the skilled artisan would not be motivated to combine the references because the carbon discs do not generate dust.¹⁰¹ The court did indicate that if no dust was produced by the action of carbon brakes, there would be no motivation for one to combine the references, and the rejection could not stand.¹⁰² However, the applicants did not provide the necessary evidence to show a lack of dust generation.¹⁰³ Therefore, the court held that there was ample motivation to combine the references.

The claim in *Wiseman* contained the limitation, “to transfer water-based steam and vaporized gasses emanating from the disc material from between adjacent discs caused by heating during a braking action.”¹⁰⁴ The Board had found that the prior art brake, when provided with grooves, would inherently overcome the steam or vapor cause of the problem. In addressing this limitation, the court noted that the appellants were “arguing that a structure suggested by the prior art, and hence, potentially in the possession of the public, is patentable to them because it also possesses an inherent, but hitherto unknown, function which they claim to have discovered. This is not the law.”¹⁰⁵

The limitation at issue in *Wiseman* was again a predictable outcome of an obvious combination of references. Because of the predictable properties of physics

and the mechanical arts, one of skill in the art at the time of invention would have readily recognized that steam generated by heat from the braking action would escape through grooves in the brakes. Instead of indicating that the property was an inherent and unknown function, the court could have reasoned that the property was predictable and carried no weight in overcoming the rejection.

We believe that a focus on the predictability of an outcome or element in an obviousness analysis provides a better context in which to address claimed properties that are the inevitable outcome of prior art teachings. If one of skill in the art could have predicted, based on the prior art teachings, that the claimed invention would possess the claimed property, the property adds no patentable weight to the claim. If, on the other hand, one of skill in the art could not have

⁹⁵*Id.* at 693 (“There is no question that all evidence of the properties of the claimed compositions and the prior art must be considered in determining the ultimate question of patentability, but it is also clear that the discovery that a claimed composition possesses a property not disclosed for the prior art subject matter, does not by itself defeat a *prima facie* case.”).

⁹⁶*Id.* at 694.

⁹⁷*Id.* (“[A]fter the PTO made a showing that the prior art compositions suggested the claimed compositions, the burden was on the applicant to overcome the presumption of obviousness that was created, and that was not done. For example, she produced no evidence that her compositions possessed properties not possessed by the prior art compositions. Nor did she show that the prior art compositions and use were so lacking in significance that there was no motivation for others to make obvious variants. There was no attempt to argue the relative importance of the claimed compositions compared with the prior art.”).

⁹⁸*In re Wiseman*, 596 F.2d 1019 (CCPA 1979).

⁹⁹*Id.* at 1021.

¹⁰⁰*Id.* at 1022 (“The board has made out a sufficient *prima facie* case of obviousness of the subject matter as a whole from Ruppe in view of Benini. One of ordinary skill in the brake art, looking to Benini in search of a solution to the problem of brake fading, would find ample suggestion therein to modify the Ruppe structure by providing grooves in the frictional surfaces of the carbon disc braking members to arrive at the claimed structure.”).

¹⁰¹*Id.* at 1021.

¹⁰²*Id.* at 1022 (“Appellants have argued that there would be no reason to combine the Benini dust-removing grooves into the Ruppe brake because carbon brakes have no dust problem. This is a significant argument.... If no dust is produced by the action of carbon brakes, there would be no motivation for one skilled in the art to incorporate Benini’s grooves into the Ruppe brake. We would then confront a situation involving no *prima facie* case of obviousness and the rejection could not stand.”).

¹⁰³*Id.* (“This argument, however, must fail. We find no evidence of record to support this assertion. We have examined **all** of the prior art of record and cannot find any support for what we therefore view as mere unsupported argument.”).

¹⁰⁴*Id.* at 1020.

¹⁰⁵*Id.* at 1023.

predicted the property, the property adds patentable weight. By using predictability, the inherency confusion is avoided.

We are, however, burdened at present with the doctrine of inherent obviousness. When faced with a rejection based on inherent obviousness, an applicant should assess whether one of skill in the art could have predicted the claimed outcome or property based on the knowledge in the art at the time of the invention. A lack of predictability indicates that the rejection is not properly supported. The examiner cannot rely on the inherent result or property as the motivation or reason to combine the references. Like-

wise, the examiner cannot use inherency to predict an expectation of success. If the outcome is unpredictable, applicant may be able to reframe the issue as an unexpected result.

The ultimate question in an inherent obviousness rejection is whether the benefit is predictable based on what was known in the art at the time of the invention. If, at the time of the invention, one could not have predicted the outcome based on the knowledge in the art, there is no inherent obviousness, and hence, no *prima facie* case of obviousness.

• • •