

2010-1308
(Serial No. 12/167,859)

United States Court of Appeals
FOR THE FEDERAL CIRCUIT

In Re HUAI-HUNG KAO, ANAND R. BAICHWAL,
TROY MCCALL, and DAVID LEE,

Appellants.

ON APPEAL FROM THE UNITED STATES PATENT AND TRADEMARK OFFICE,
BOARD OF PATENT APPEALS AND INTERFERENCES

**COMBINED PETITION FOR REHEARING AND FOR
REHEARING *EN BANC* BY APPELLANTS**

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June 23, 2011

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, Jeffrey I.D. Lewis, counsel for Appellants, certifies the following:

1. The full name of the parties represented by me is:

Huai-Hung Kao, Anand R. Baichwal, Troy McCall and David Lee

2. The name of the real party in interest is:

Endo Pharmaceuticals Inc. Additionally, Penwest Pharmaceuticals Co., now a subsidiary of Endo Pharmaceuticals Inc., is affected by the outcome of this case.

3. All parent corporations and any publicly held companies that own ten percent or more of the stock of the parties represented by me are:

Endo Pharmaceuticals Inc. is a subsidiary of Endo Pharmaceuticals Holdings Inc.

4. The names of all law firms and the partners or associates that appeared for the party now represented by me in the trial court or agency or are expected to appear in this court are:

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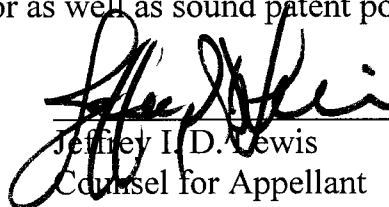
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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the May 13, 2011 precedential Panel opinion in *In re Kao*, 2010-1308, is contrary to 35 U.S.C. § 103(a) and precedent including *In re Spormann*, 363 F.2d 444 (CCPA 1966); *In re Adams*, 356 F.2d 998 (CCPA 1966); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565 (Fed. Cir. 1986), *overruled in part on unrelated grounds by Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, 383 F.3d 1337 (Fed. Cir. 2004); *In re Rijckaert*, 9 F.3d 1531 (Fed. Cir. 1993); and *Cohesive Tech., Inc. v. Waters Corp.*, 543 F.3d 1351 (Fed. Cir. 2008). If the Panel decision is allowed to stand, it also could negate method of use claims for previously-known compounds thereby discouraging innovation against the Constitutional mandate to promote progress.

This Petition requires resolution of the following issue of exceptional importance:

If an element of a method claim is not disclosed or suggested to those of ordinary skill by the prior art, but is labeled as an inherent property, may that putative inherent property serve to render the claim “as a whole” obvious under 35 U.S.C. § 103(a) contrary to the precedent of this Court and its predecessor as well as sound patent policy?



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**COMBINED PETITION FOR REHEARING AND
FOR REHEARING *EN BANC***

Section 103(a) of Title 35 U.S.C. mandates that for obviousness one must consider “the subject matter as a whole ... at the time the invention was made” from the vantage point of “a person having ordinary skill in the art to which said subject matter pertains.” Here, the Panel affirmed an obviousness rejection even though all agree that an express element of the claims is not in the prior art and would not be recognized by those of ordinary skill prior to being disclosed in the application. Since it was not within the knowledge base of those having ordinary skill in the art “at the time the invention was made,” obviousness of “the subject matter as a whole” cannot be established in accordance with the plain language of § 103(a), the underlying Congressional intent, and precedent. To hold otherwise, as the Panel’s precedential opinion did, discourages future research and advances.

The precedential Panel decision is contrary to precedent (*see* Section C below), not supported by the two cited cases (*see* Section D) and against the good public policy of encouraging improvements and new uses for known inventions (*see* Section A). The important issues raised directly effect obviousness and the patentability of many claims both under consideration and issued.

ARGUMENT

Judge Rich stated that nonobviousness under § 103 “is the heart of the patent system and the justification of patent grants.” Hon. Giles S. Rich, *Ghost of the*

“Invention” Requirement, Nonobviousness – The Ultimate Condition of Patentability, Ed. John F. Witherspoon, 1:501. That section was enacted to stabilize case law beginning with *Hotchkiss v. Greenwood*, 52 U.S. 248 (1850), and developed in common law for over a century. *Graham v. John Deere Co.*, 383 U.S. 1, 15 (1966). It requires that obviousness be determined [1] from the viewpoint and knowledge of one of ordinary skill in the art [2] at the time of the invention [3] considering the invention “as a whole,” thereby excluding hindsight based upon the inventor’s own disclosure. For that reason, obviousness rejections “must be based on evidence comprehended by the language of that section.” *In re Grasselli*, 713 F.2d 731, 739 (Fed. Cir. 1983) (citation omitted).

Nonetheless, a Panel of this Court disregarded the statute’s requirements. The Panel determined that a single element, outside of the claimed method as a whole, could be considered “inherent” even though there is no evidence that it was disclosed in the prior art or that one of skill in the art would have understood the property to be a necessary consequence of the prior art at time of invention.

While *arguendo* inherency might be relevant to claims covering the prior art (such as for the active compound itself, oxymorphone),¹ that is not what Applicants

¹ *Cf. In re Wiseman*, 596 F.2d 1019, 1023 (CCPA 1979) (rejection upheld where “solution is obvious from prior art which contains the same solution for a similar problem” because “[a] patent on such a structure would remove from the public
(... footnote continued)

claimed. The claims (at A3) are to a controlled release method of treatment that achieves a biological effect, *i.e.*, the maximum concentration of oxymorphone after administering the described controlled release formulation “is at least about 50% higher when the dosage form is administered to the subject under fed versus fasted conditions” (the “food effect”). However, the Panel decision affirmed obviousness because the food effect was called inherent to oxymorphone, even if unappreciated before Applicants’ disclosure.

A. The Panel’s Decision Discourages Innovation

The Panel’s broad obviousness-by-inherency standard discourages innovation and improvements on previously-known inventions. *See* 35 U.S.C. § 101 (“new and useful improvement” is patentable); *see also Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368, 1378-79 (Fed. Cir. 2005) (“New uses of old products or processes are indeed patentable subject matter”); *Catalina Mkt’g Int’l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 809-10 (Fed. Cir. 2002) (patent to a compound does not foreclose subsequent patent on a new method of using it). Allowing it to stand uncorrected is contrary to the Constitutional mandate of “promot[ing] the Progress of ... useful Arts.” U.S. Const. Art. I § 8 ¶8.

that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art.”).

The Panel's decision would bar claiming a new method of treatment using a known medicine (*e.g.*, discovering that the proverbial cure for cancer is a new use of an old compound). Even if the use is novel and not what is expected by those of ordinary skill in the art at the time, the Panel decision would render it unpatentable because the effect would be inherent in the compound's use; although beneficial and previously unknown, the use would be deemed "inherent" to the compound. *Cf. Catalina*, 289 F.3d at 809-10 (supporting patentability of "the new use of the [known] compound"). That is what this Court said to *exclude* from the inherency doctrine. *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373, 1381 (Fed. Cir. 2003) (a compound inherently in the prior art is not patentable but claims to administering the metabolite or corresponding pharmaceutical composition may be); *see also Smithkline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1346 (Fed. Cir. 2005) ("a patentee may obtain patent protection for an inherently anticipated compound through proper claiming").

As set out below, the Panel decision treated the claims as if they are directed to the prior art compound oxymorphone itself, when they actually are to a method of treatment using a novel oxymorphone formulation. Therefore, the Panel erred by relying on so-called "inherent" but previously unknown properties of oxymorphone to reject the method claims at issue. *See In re Adams*, 356 F.2d at 1002-3; *Kloster Speedsteel*, 793 F.2d at 1576; *Perricone*, 432 F.3d at 1379 (*e.g.*,

“In other words, the district court’s inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent.”). Section 103(a) asks what those of skill in the art knew as a whole at time of invention – that is the standard for a “new and useful improvement.” *See Graham*, 383 U.S. at 15. For the Panel to have considered inherent properties of one element based only upon the application’s teaching of the improvement is improper and supports granting this Petition.

B. The Panel Decision

In its precedential May 13, 2011 opinion (consolidated with Appeals 2010-1307 and -1309 for opinion purposes, but this Petition only addresses for Appeal No. 2010-1308), a Panel of this Court affirmed an obviousness rejection by isolating the food effect element from the claims as a whole and then declaring that this otherwise unknown element is “inherent” in the prior art – even though the only cited indication of the food effect was Applicant’s specification (A10).

The claims on appeal are for a method of treating chronic pain in humans by administering a controlled release, 12-hour oxymorphone formulation and achieving the food effect. (*See* A3.) They were rejected as obvious, but not anticipated. (*See* Slip Op. 8-9.) (These claims are to an important commercial product, although the Panel decision discussed the Secondary Considerations primarily in relation to another appealed application, *see* Slip. Op. 24 and 16-20.)

The Office admitted that the claimed formulation is not found identically in the prior art, the food effect is not found or suggested in the cited prior art, and the prior art does not disclose the administration of a controlled release oxymorphone formulation to patients.

The Panel, however, ignored the contradiction between an unknown “inherent” property and what those of ordinary skill actually would have appreciated at the time of invention. *See, e.g., Kloster Speedsteel*, 793 F.2d at 1576 (not obvious when “...fail[ed] to establish that that inherency would have been obvious to those skilled in the art when the invention ... was made.”). The Panel relied on a single reference, Maloney, but Maloney discloses only *in vitro* results from controlled release formulations of a different opioid drug, does not contain any example using oxymorphone, and does not provide human testing results for *any* controlled release opioid formulation. (A6-8.) Yet because Maloney included oxymorphone in its list of opioids, the Panel found that Maloney’s failure to disclose the food effect was irrelevant because that effect was inherent to oxymorphone and therefore not of “patentable consequence”:

“... Further, the Office responds that inherency is indeed a part of the obviousness inquiry.

“This court agrees with the Office. Substantial evidence supports the Board’s finding, based upon the specification, which confirms that the claimed ‘food effect’ is an inherent property of oxymorphone itself, present both in controlled release and immediate release formulations of that drug. *See In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009)

(stating ‘[e]ven if no prior art of record explicitly discusses the [limitation], [applicant’s] application itself instructs that [the limitation] is not an additional requirement imposed by the claims on the [claimed invention], but rather a property necessarily present in [the claimed invention]’); *see also King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1275-76 (Fed. Cir. 2010) (stating that ‘merely discovering and claiming a new benefit of an old process cannot render the process again patentable’ (citations omitted)). This is not a case where the Board relied on an unknown property of prior art for a teaching. Rather, Maloney’s express teachings render the claimed controlled release oxymorphone formulation obvious, and the claimed ‘food effect’ adds nothing of patentable consequence.”

Slip Op. at 21-22. As set out in Section D below, the two cited cases do not apply and the Panel ignored contrary precedent.

C. Obviousness Must Be Based On What Those Skilled In the Art Understood

Obviousness must be based upon the expectations of those having ordinary skill in the art using their knowledge at the time of invention – not some hindsight recreation. *In re Foster*, 343 F.2d 980, 990 (CCPA 1965) (“unobviousness ... must be determined as of ‘the time the invention was made’ without utilizing after-acquired knowledge”). The drafters of § 103 expressly wanted “to ‘guard against slipping into use of hindsight,’ and to resist the temptation to read into the prior art the teachings of the invention in issue.” *Graham*, 383 U.S. at 36 (citation omitted); *see In re Foster*, 343 F.2d at 990 (“the words ‘at the time the invention was made’ were included for the sole purpose of precluding the use of hindsight in deciding whether an invention is obvious.”). Using an application’s own teaching as the only evidence to support obviousness, as done here (A10), must be the

quintessential example of hindsight in violation of §103(a).

Section 103 requires claims be considered *as a whole* based upon what those of skill understood *at time of invention*, elements cannot be parsed and considered piecemeal. Judge Rich, one of the principal drafters of § 103, explained:

Section 103 speaks of a condition of *patentability* instead of ‘invention.’ ... The unobviousness is *as of a particular time and to a particular* legally fictitious, technical person, analogous to the ‘ordinary reasonable person’ so well known to courts as a legal concept. To protect the inventor from hindsight reasoning, the time is specified to be *the time the invention was made* ... But *that* is not all; *what* must have been obvious is the ‘*subject matter as a whole.*’ ... If, for example, a *combination* is claimed, section 103 requires that to invalidate the claim, it must be shown that the *combination* was obvious, not merely its components.

Ghost of the “Invention” Requirement, Nonobviousness – The Ultimate Condition of Patentability, Ed. John F. Witherspoon, 1:508 (emphasis in original). If it was known to those of ordinary skill at time of invention, then it is part of the obviousness analysis; if it was not known, then it is not part of the analysis.

Obviousness under § 103(a) cannot be premised on a not-yet-known property, even if it is inherent:

[T]he inherency of an advantage and its obviousness are entirely different questions. *That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown.*

In re Spormann, 363 F.2d at 448 (emphasis added) (citing *In re Adams*, 356 F.2d 998 (CCPA 1966)); see also Manual of Patent Examination Procedures § 2141.02 (Eighth Ed., Rev. 8) (“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” (citing *In re Rijckaert*, 9 F.2d 1531)). *In re Adams* the CCPA drew the appropriate distinction between inherent properties and the knowledge of those in the art:

[T]he solicitor adds the argument that the superiority of appellant’s heat transfer is inherent in the use of foam. Again we observe that, of course, it is. But the art does not suggest the use of foam in heat transfer of any kind and *there is not the slightest suggestion that anyone knew of the existence of this inherent superiority until Adams disclosed it.* ... Two of our decisions are cited as supporting the erroneous notion that ‘subject matter cannot be patented on the basis of an inherent property.’ *We think the proposition thus broadly stated and as applied here is so transparently erroneous as not to require discussion.*

356 F.2d at 1002-3 (emphasis supplied); see *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1350-52 (Fed. Cir. 2008) (applying *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), test that patent not likely invalid as inherently obvious).

This Court’s and the CCPA’s precedent establish that when claim elements are not in the prior art, the claim cannot be held obvious if the “inherent” element is not recognized to those of ordinary skill at time of invention. For instance:

- *Cohesive Tech.*, 543 F.3d at 1364 & n.2 (“Although anticipation can be proven inherently, proof of inherent anticipation is not the same as proof of obviousness.” (collecting cases));
- *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296 (Fed. Cir. 2002) (“[O]bviousness is not inherent anticipation.”);
- *In re Grasselli*, 713 F.2d at 739 (reversing § 103 rejections based upon declarations that only created “*inferences of inherency* ...” (emphasis in original));

- *Kloster Speedsteel*, 793 F.2d at 1576 (“Inherency and obviousness are distinct concepts,” and claim was not obvious where no evidence showed that the “inherency would have been obvious to those skilled in the art when the invention ... was made.” (internal citations omitted));
- *In re Spormann*, 363 F.2d at 448 (reversing where Board improperly took “judicial notice” of element without a reference disclosing it);
- *In re Rijckaert*, 9 F.3d at 1533-34 (reversing the Board’s decision that an element “was somehow ‘inherent’ in the prior art” when the prior art did not disclose or suggest the claimed feature);
- *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1345 (Fed. Cir. 2008) (district court “incorrectly suggested, in a footnote, that obviousness is subsumed by inherency”); and
- *In re Fracalossi*, 681 F.2d 792, 796 (CCPA 1982) (Miller, J., concurring) (“it does not follow that every technically anticipated invention would also have been obvious”).

Inherency may be appropriate for anticipation under § 102, but not for obviousness. As explained in *Schering*, an inherent property previously practiced in the prior art is not patentable under § 102 because “granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated.” 339 F.3d at 1379-1380 (quoting *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999)). But that does not extend to obviousness for a new discovery. *Schering*, 339 F.3d at 1381. For anticipation under § 102, inherency looks to whether the property is present and already “known or used” in the prior art, but obviousness only applies when “the invention is not identically disclosed or described as set forth in section 102 of this title.” 35 U.S.C. § 103(a); *see also Cohesive Tech*, 543 F.3d at 1364

n.2 (§ 102 is not ‘subsumed’ by § 103).

It is well established that prior art is treated differently under § 103 and § 102. For instance, an anticipation rejection can be rebutted by showing that the reference is not enabled (*Elan Pharmaceuticals, Inc. v. Mayo Foundation*, 346 F.3d 1051 (Fed. Cir. 2003) (*en banc*)), but that cannot be used for obviousness (*Symbol Techs. Inc. v. Opticon Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991)). Similarly, “obviousness requires analysis of secondary considerations ... while secondary considerations are not an element of a claim of anticipation.” *Cohesive*, 543 F.3d at 1364 (collecting cases comparing standards); *see e.g., In re Wiggins*, 488 F.2d 538, 543-44 (CCPA 1973) (*accord*); *Graham*, 383 U.S. at 17-18.

The Panel in this case has ignored precedent to the contrary, as set out above. As a matter of law and procedure, subsequent panels must follow the binding precedent of an earlier panel. *E.g., Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988) (“This Court has adopted the rule that prior decisions of a panel of the court are binding precedent on subsequent panels unless and until overturned *en banc*.”). Accordingly, this Petition should be granted.

D. The Panel’s Incorrect Reliance on *Kubin* and *King*

The two cases cited by the Panel are *Kubin* and *King*, but they do not support the decision. The citations deal with anticipation, which does not require any recognition of the inherent element by one skilled in the art. To the extent that

either case can be applied to obviousness, each decision found that one of skill in the art would have *recognized* the claimed property in the prior art despite the absence of an express disclosure in the prior art (unlike this appeal).

The prior art in *Kubin* both disclosed the claimed structure and suggested the inherent feature. Those claims were for a polypeptide called “NAIL” that binds to the CD48 receptor. *Id.* at 1352-53. The record showed that NAIL was actually the previously-disclosed “P38” polypeptide. *Id.* at 1354. The Board found that “one of ordinary skill in the art would have *recognized* the value of isolating the gene sequence of NAIL” based on the prior art P38 disclosures. *Id.* at 1355 (emphasis added). Accordingly, the *Kubin* opinion sustained the Board’s finding that all of the elements could be derived from the prior art. *Id.* at 1357. Here, for Kao et al., no evidence shows the claimed method was present in the prior art nor that one of skill in the art would have recognized the food effect before it was disclosed in Applicants’ specification. (A10.)

The *King* case also does not support the Panel’s holding. First, the decision reversed the lower court’s § 101 holding because it “ignored the claim as a whole,” 616 F.3d at 1280 (*see also id.* at 1277), much as the Panel here did in applying § 103. Second, the cited portion of *King* addressed anticipation, not obviousness, stating “the preamble to claim 1 is inherently anticipated” because “[t]o hold otherwise would remove from the public a method of treating muscle pain that has

been performed for decades.” *Id.* at 1276 (emphasis supplied). (Separately, dependent claims were held obvious because the prior art, Dent, “disclosed [the element] ... [so] it would be obvious ... to combine Dent’s teaching of [the element].” *Id.* at 1281.) *King* does not address the obviousness of claim 1, only anticipation, and it cannot support extending inherency to obviousness.

E. On the Instant Facts, There Is No Obviousness

The undisputed facts are that: [1] the only rejection is for obviousness under § 103(a), not anticipation under § 102; [2] all claims require the food effect; [3] obviousness was affirmed based on only one reference, Maloney; [4] Maloney does not disclose the food effect limitation (nor does any other reference); and [5] the Office found the first disclosure of the food effect was in Applicants’ specification (A10). To reject a claim under § 103(a), the prior art must disclose or render obvious to one of skill in the art each and every limitation of the claims at time of invention, *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970), and here the prior art of record does not do so.

The only cited food effect teaching is Applicants’ disclosure (A10), as even the Office’s merits brief (at p. 9) acknowledged. That disclosure is not evidence and cannot support *prima facie* obviousness. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991); *In re McNeil-PPC, Inc.*, 574 F.3d 1393, 1400 (Fed. Cir. 2009); *In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009). At most, inherency may be

considered in obviousness when one of ordinary skill would recognize the element labeled inherent, but there is no such showing of that in this case. Since no one of ordinary skill in the art knew of the food effect before disclosure, there is no showing of obviousness "at the time of the invention" and the rejection should have been reversed.

CONCLUSION

For the reasons set forth above, Appellant respectfully submits that the Panel decision in this case, 2010-1308, should be vacated and the rejection reversed.

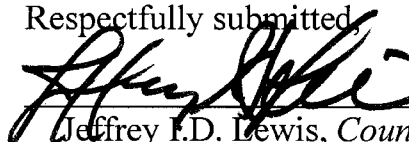
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