

# United States Court of Appeals for the Federal Circuit

05-1284

FERRING B.V.,

Plaintiff-Appellant,

and

AVENTIS PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

BARR LABORATORIES, INC.,

Defendant-Appellee.

Dennis J. Mondolino, Morgan, Lewis & Bockius, LLP, of New York, New York, argued for plaintiff-appellant Ferring B.V. With him on the brief were Stephen B. Judlowe, Esther H. Steinhauer, Edward M. Reisner, Jeffrey M. Gold, and Timothy P. Heaton.

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Appealed from: United States District Court for the Southern District of New York

Judge Charles L. Brieant

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DECIDED: February 15, 2006

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Before NEWMAN, MAYER, and DYK, Circuit Judges.

Opinion for the court by Circuit Judge DYK. Dissent by Circuit Judge NEWMAN.

DYK, Circuit Judge.

Ferring B.V. (“Ferring”) and Aventis Pharmaceuticals, Inc. (“Aventis”) brought suit against Barr Laboratories, Inc. (“Barr”) for infringement of Ferring’s patent, U.S. Patent No. 5,407,398 (filed Dec. 17, 1985) (“’398 patent”). Barr moved for summary judgment, arguing that the ‘398 patent was unenforceable due to inequitable conduct and, alternatively, that Barr did not infringe the ‘398 patent. The district court granted summary judgment on both grounds. We affirm the district court’s grant of summary judgment on the ground that the patent is unenforceable due to inequitable conduct, and we do not reach the issue of infringement.

## BACKGROUND

Ferring patented a medicinal compound and a method of administering said compound. Specifically, claim one of Ferring's '398 patent (the independent composition claim) claimed an "antidiuretic composition for humans comprising a gastrointestinally absorbable, antidiuretically effective, amount of [the peptide] 1-deamino-8-D-arginine vasopressin and a pharmaceutically acceptable carrier in solid oral dosage form for absorption in the gastrointestinal tract of said humans." '398 patent at col.4 l.23-29. 1-deamino-8-D-arginine vasopressin and other compounds were known in the art to prevent the diuretic symptoms associated with diabetes when they were absorbed through the walls of the patient's mouth via a dissolving tablet, or through the patient's nasal passage via a liquid spray or plastic tube. However, such modes of administering the medicine proved cumbersome and time-consuming. Therefore, the claimed solid oral dosage form of the compound and method of administering it were thought to be an improvement over the prior art, because the medicine was designed to be simply swallowed and absorbed through the gastrointestinal tract. As the inequitable conduct claim arises from the prosecution history of the '398 patent, we will begin there.

I

On December 17, 1985, Hans Vilhardt and Helmer Hagstam filed an application for the '398 patent.<sup>1</sup> On May 28, 1986, Vilhardt and his counsel appeared at a

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<sup>1</sup> Inventors Vilhardt and Hagstam had been employed by Ferring and, in 1984, they assigned all of their prospective rights to the '398 patent to Ferring. Prior to the prosecution at issue, the inventors had twice filed applications for their invention, and both times their application was rejected as anticipated or obvious over U.S. Patent No. 3,497,491.

preliminary interview conducted by Examiners Moyer and Stone at the Patent and Trademark Office (“PTO”). At the interview, the examiners discussed certain prior art references, including U.S. Patent No. 3,497,491 (filed Sept. 14, 1967) (“491 patent” or “Zaoral patent”). Ferring was the exclusive licensee of the ‘491 patent until its expiration in 1987. The ‘491 patent taught, for antidiuretic purposes, that “1-deamino-8-D-arginine vasopressin” “may be used . . . for the parenteral, peroral, intranasal, subcutaneous, intramuscular, or intravenous application.” ‘491 patent at col.3 l.15-23, col.5 l.15-20 (emphasis added). The examiners were concerned that the ‘491 patent’s disclosure of the “peroral” application of the peptide may have suggested the oral administration of the peptide for gastrointestinal absorption. Vilhardt argued that the term “peroral” as used in the ‘491 patent did not teach the oral administration of the peptide for gastrointestinal absorption, but rather for absorption through the walls of the mouth. As the examiners were not entirely convinced, they “suggested that applicants obtain evidence from a non-inventor” to support their interpretation of the term “peroral.” J.A. at 3460 (emphasis added).

In response, on June 12, 1986, Vilhardt, through his counsel, submitted four declarations including two from Vilhardt himself, one from a Dr. Myron Miller, and one from a Dr. Paul Czernichow. These declarations each relayed the writer’s scientific belief that the term “peroral” in the ‘491 patent meant that the compound could be administered “through the mouth,” but only for absorption through the cheek of the mouth or under the tongue. However, the declarations failed to disclose that

Czernichow had been receiving research funding from Ferring from 1985-86.<sup>2</sup> Specifically, Czernichow received research funding to conduct a clinical investigation relating to a particular drug (DDAVP) preparation.

Despite the declarations, on November 13, 1986, the examiners rejected certain claims of the '398 patent as anticipated or obvious over the '491 patent. The rejection stated: "As Applicants are the exclusive licensee of the Zaoral ['491] patent, it is obviously expeditious for Applicants to argue that 'peroral' referred to in the ['491] patent referred only to sublingual or buccal routes, whereas the instant mode of administration excludes such routes as it involves absorption by the gastrointestinal tract." J.A. at 4390.

The inventors requested reconsideration after which a new examiner, Examiner Siegel, reaffirmed the rejections. Examiner Siegel stated that the '491 patent "clearly teaches orally administering said vasopressin," and that "oral administering of a drug . . . unambiguously means gastrointestinal absor[p]tion." J.A. at 3067.

On November 13, 1987, the inventors appealed this rejection to the Board of Patent Appeals and Interferences ("Board"). On September 21, 1990, the Board accepted the declarants' view that, as a general rule, the "peroral" administration of a peptide would not be read in the art as suggesting the administration for gastrointestinal absorption. This is because peptides are normally "hydrolyzed in the stomach and it would be expected that their biological activities would be lost" prior to gastrointestinal absorption. J.A. at 3688. Thus, the '491 reference standing alone would not anticipate

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<sup>2</sup> Czernichow testified that he was not receiving funding from Ferring in June 1986, when he submitted his first declaration.

the applicant's claims regarding the peroral administration of the peptide. However, the Board determined that the applicants' claims were obvious over the '491 patent in light of an article written by Ivan Vavra in 1973. Vavra disclosed that 1-deamino-8-D-arginine vasopressin is structurally unique among peptides in that it does not degrade quickly. The Board found that although the term "peroral" may not usually suggest the gastrointestinal absorption of a peptide, the '491 patent's disclosure of the "peroral" administration of 1-deamino-8-D-arginine vasopressin, when combined with Vavra's disclosure that this peptide is slow to degrade, would render the applicant's claims obvious. The Board thus affirmed the examiners' obviousness rejection. However, because the examiners had not relied on the Vavra reference, the Board designated its decision as "a new rejection under the provisions of 37 C.F.R. [§] 1.196(b)," and explained that the applicant could "elect to have further prosecution before the examiner in response to the new rejection . . . ." J.A. at 3690.

The inventors opted to go back to the examiners. On November 21, 1990, the inventors submitted five more declarations to persuade the examiners that the Vavra reference would not, when read with the '491 patent, suggest the gastrointestinal absorption of the peptide. As before, the inventors submitted declarations from Vilhardt, Miller, and Czernichow. They also submitted declarations from a Dr. Iain Robinson and a Dr. Tomislav Barth. Each of these declarations explained why, in the declarant's own professional judgment, the Vavra reference did not suggest that the peptide could be absorbed gastrointestinally. Just as before, the inventors did not inform the examiners

that Czernichow had been receiving funds from Ferring.<sup>3</sup> This time, however, they also failed to inform the examiners that Robinson (one of the new declarants) had been Ferring's pre-clinical research director from 1985-1986 and a paid consultant for Ferring from 1986-1989. While Robinson was the research director at Ferring, Ferring was funding Vilhardt's research involving the peptide at issue. The inventors also did not disclose that Barth (another new declarant) worked on several projects funded by Ferring between 1984 and 1987. Barth also worked intermittently with Vilhardt on some small projects between 1988 and 2000, although it is unclear from Barth's testimony whether this research was funded by Ferring. Neither Robinson's nor Barth's declarations were accompanied with a Curriculum Vitae ("CV"). Czernichow's declaration did include an extensive CV. However, it did not mention his research with Ferring.

Vilhardt communicated with each of these declarants before their declarations were submitted to the PTO. Vilhardt also sent Barth a "draft declaration." While it is unclear exactly what was contained in the draft declaration, Vilhardt admitted that he gave Barth "some lines," telling him "what he should describe in the affidavit." J.A. at 5544. Vilhardt also sent Robinson a "draft declaration."

In sum, four of the five declarations submitted to the PTO in 1990 were written by scientists who had been employed or had received research funds from Ferring, and Vilhardt participated in the drafting of two of the four declarations submitted by non-inventors. The examiners were not otherwise made aware of the Ferring connections. After these declarations were submitted, the examiners allowed the previously rejected

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<sup>3</sup> It is unclear from the record whether Czernichow was receiving research funding at the very time he drafted his second declaration.

claims, and the '398 patent issued on September 10, 1991. The PTO did not provide any explanation for its allowance.

## II

Ferring exclusively licensed the right to market and sell its patented antidiuretic compound to Aventis.<sup>4</sup> In July 2002, Barr filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration, seeking approval to market a generic version of the compound at issue. In connection with its ANDA, Barr filed a so-called “paragraph IV certification,” which is a statement that any relevant patents to the generic compound are either invalid or will not be infringed. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (2000). Barr’s paragraph IV certification claimed that the ‘398 patent was invalid. In response, Ferring filed an infringement action against Barr pursuant to 35 U.S.C. § 271(e)(2). Barr moved for summary judgment based on inequitable conduct and non-infringement. The district court granted summary judgment to Barr on both grounds. On the issue of inequitable conduct, the district court found:

The undisputed evidence in this case supports the finding of inequitable conduct by the patentee and its agents and the grant of summary judgment. The reluctance of the PTO to issue the ‘398 patent was evident. Each affidavit submitted in support of its issuance was thus highly material to the prosecution history. That three of the challenged declarations were submitted after several iterations of rejected attempts to obtain the patent’s issuance speaks loudly as to motive and intent. While credibility determinations from a courtroom observation may at times be necessary on the issue of intent, here, the entire record presents clear and convincing evidence of an intent to mislead the examiners, even viewing the evidence, as it must be viewed, in the light most favorable to Plaintiff. The submission

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<sup>4</sup> The salt form of 1-deamino-8-D-arginine vasopressin, “DDAVP,” is the actual product at issue here. Ferring and Barr disagree as to whether DDAVP is covered by the ‘398 patent. Because our opinion is confined to the inequitable conduct issue, we do not reach Barr’s non-infringement claim, which would require us to resolve whether DDAVP is covered by the patent.

of the Czernichow and Robinson declarations, and to a lesser extent that of Barth, support a finding of intent to mislead the PTO.

J.A. at 18. The court specifically found that “it must have been clear to Dr. Vilhardt at the preliminary meeting with the examiner that a non-inventor affidavit was sought for purposes of obtaining objective evidence that the invention was not anticipated by the prior art or obvious.” J.A. 16 (emphasis added). Ferring and Aventis timely appealed.

## DISCUSSION

Appellants argue that the district court erred in granting summary judgment to Barr on both the issues of inequitable conduct and infringement. Because we find that the district court properly granted summary judgment to Barr on the inequitable conduct ground, we do not reach the infringement issue.<sup>5</sup>

“Inequitable conduct occurs when a patentee breaches his or her duty to the PTO of ‘candor, good faith, and honesty.’” Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1342 (Fed. Cir. 2005) (quoting Mollins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). While inequitable conduct includes affirmative misrepresentations of material facts, it also arises when the patentee fails to disclose material information to the PTO. Id.; Pharmacia Corp. v. Par Pharm., Inc., 417 F.3d 1369, 1373 (Fed. Cir. 2005). “The inequitable conduct analysis is performed in two steps comprising ‘first, a determination of whether the withheld reference meets a threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent in light of all the circumstances to determine whether the applicant’s conduct is so culpable that the patent should be held unenforceable.’”

Dayco Prods., Inc. v. Total Containment, Inc., 329 F.3d 1358, 1362-63 (Fed. Cir. 2003) (quoting Purdue Pharma L.P. v Boehringer Ingelheim GMBH, 237 F.3d 1359, 1366 (Fed. Cir. 2001)). The predicate facts must be proven by clear and convincing evidence. Id. at 1362. “While our precedent urges caution in the grant of summary judgment respecting a defense of inequitable conduct, summary judgment is not foreclosed.” Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1190 (Fed. Cir. 1993); see also Digital Control Inc. v. The Charles Machine Works, -- F.3d -- , slip op. at 6 (Fed. Cir. 2006) (“Determining at summary judgment that a patent is unenforceable for inequitable conduct is permissible, but uncommon.”).

I

We first consider the district court’s determination that there were no genuine issues of material fact with respect to materiality and intent. Our review in this respect is without deference. Dayco Prods., 329 F.3d at 1362-63.

A. Materiality

For patent applications that have been prosecuted prior to 1992, we have held that “[i]nformation is deemed material if there is a substantial likelihood that a reasonable examiner would have considered the information important in deciding whether to allow the application to issue as a patent.” Li Second Family L.P. v. Toshiba Corp., 231 F.3d 1373, 1379 (Fed. Cir. 2000) (quoting 37 C.F.R. § 1.56 (1989)); Syntex (U.S.A.) LLC v. Apotex, Inc., 407 F.3d 1371, 1384 (Fed. Cir. 2005).<sup>6</sup> We have made

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<sup>5</sup> See, e.g., GFI, Inc. v. Franklin Corp., 265 F.3d 1268, 1275 (Fed. Cir. 2001) (finding infringement issues moot after patent was deemed unenforceable due to inequitable conduct).

<sup>6</sup> Although the PTO amended the language of 37 C.F.R. § 1.56 in 1992, we have continued to use the pre-1992 language regarding materiality for evaluating

clear that examiners have broad authority to request information that they deem relevant to the issue of patentability. Star Fruits S.N.C. v. United States, 393 F.3d 1277, 1283 (Fed. Cir. 2005). In response to requests from examiners, applicants frequently submit supporting declarations. Given the ex parte nature of proceedings before the PTO, it is especially important that the examiner has all the information needed to determine whether and to what extent he should rely on declarations presented by the applicant.

The general law of evidence has long recognized that the testimony of any witness may be rendered suspect by a past relationship with a party.<sup>7</sup> The pertinent rules for PTO examiners have specifically recognized this evidentiary principle, explaining: “Affidavits or declarations should be scrutinized closely and the facts presented weighed with care. The affiant’s or declarant’s interest is a factor which may be considered, but the affidavit or declaration cannot be disregarded solely for that reason.” J.A. at 5415 (The Manual of Patent Examining Procedure). As appellants concede, we have previously held that a declarant’s prior relationships with the patent

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patents that were prosecuted before the amendment. See Dayco Prods., 329 F.3d at 1363-64. Prior to the amendment, the relevant portion of § 1.56 read: “information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” 37 C.F.R. § 1.56(a) (1991). See also Digital Control Inc., -- F.3d at --, slip op. at 7-12 (finding that “the new Rule 56 was not intended to replace or supplant the ‘reasonable examiner’ standard,” and recognizing that the case law supports several standards of materiality).

<sup>7</sup> See United States v. Robinson, 530 F.2d 1076, 1079-80 (D.C. Cir. 1976) (finding a witness’s past business transactions with a party significant in assessing the witness’s credibility); Aetna Ins. Co. v. Paddock, 301 F.2d 807, 812 (5th Cir. 1962) (finding a witness’s past financial affiliation with a party significant in assessing his credibility); see also 3A Wigmore, Evidence § 949, at 786 (Chadbourn rev. 1983) (“The relation of employment, present or past, by one of the parties, is also usually relevant.”).

applicant may be material, and that failure to disclose such relationships to the examiner may constitute inequitable conduct. Refac Int'l, Ltd. v. Lotus Dev. Corp., 81 F.3d 1576, 1581-82 (Fed. Cir. 1996); Paragon, 984 F.2d at 1191-92.

In Refac, the PTO examiner rejected an application because it did not sufficiently enable one skilled in the art to make the invention. 81 F.3d at 1578. The examiner stated that a supporting affidavit by the co-inventor had very little probative value and was “self serving.” Id. In response, the inventors suggested that they submit affidavits from people “other than the inventors” to support the sufficiency of the disclosure. Id. They then submitted affidavits from three individuals but failed to disclose that at least one of the individuals had worked for the inventors’ company for a short eight-week period and was already familiar with the invention. Id. at 1580-81. We affirmed the district court’s finding that this omission was material and supported a finding of inequitable conduct. Id. at 1581-82. In so doing, we found it particularly important that “[a]n examiner must be able to evaluate information in an affidavit in context, giving it the proper weight . . . .” Id. at 1583.

In Paragon, the examiner requested “disinterested third party” declarations and when the inventors submitted the declarations, they failed to disclose that one of the declarants owned stock in the assignee’s company at the time of his declaration and had previously been a consultant for the company. 984 F.2d at 1191. The declarant also averred in his declaration that he had not been “employed” by the assignee’s company. Id. We decided not to “quibble about whether a ‘consultant’ is or is not ‘employed’ by a company,” finding instead that the declarant was not “a ‘disinterested’

party in any recognized sense of the word.” Id. at 1192. We then affirmed a finding of inequitable conduct based on omissions regarding the declarant’s affiliations. Id.

Here, appellants argue that the Ferring affiliations of declarants Czernichow, Robinson, and Barth, were immaterial as a matter of law because (1) those affiliations supposedly did not bear directly on the critical assertion that each made in his declaration, meaning that the relationships were not the source of the information in the declarations, and (2) the declarants did not have a direct financial stake in the success of the patent.

Our jurisprudence does not suggest such a narrow view of materiality.<sup>8</sup> A witness’s interest is always pertinent to his credibility and to the weight to be given to his testimony, and relevant interests are not limited to direct financial interests. Under Refac and Paragon, a declarant’s past relationships with the applicant are material if (1) the declarant’s views on the underlying issue are material and (2) the past relationship to the applicant was a significant one. Here we think that each of these requirements was satisfied on the summary judgment record.

First, we agree with the district court that the declarations themselves were “highly material.”<sup>9</sup> The Board itself relied on Czernichow’s first declaration for the

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<sup>8</sup> Contrary to appellants’ assertions, Juicy Whip v. Orange Bang, Inc., 292 F.3d 728 (Fed. Cir. 2002) did not limit the relevance of particular affiliations to those where the affiliation gave the declarant specialized knowledge relating to his declarations. Juicy Whip simply held that the substance of an affidavit may be immaterial where the facts asserted therein were undisputed. See id. at 744. There is no concession in this case that the declarants’ views as to the meaning of the term “peroral” in light of the Vavra reference were undisputed during prosecution.

<sup>9</sup> “While it is not necessary to cite cumulative prior art because it adds nothing to what is already of record (although it may be prudent to do so), one cannot excuse the submission of a misleading affidavit on the ground that it was only cumulative.

“general rule” that “peroral” would not be read by those in the art to suggest the gastrointestinal absorption of peptides. While the Board went on to reject the claims in light of the Vavra reference, Czernichow’s declaration certainly advanced the applicants’ argument. Moreover, the second set of declarations, which was plagued with even more undisclosed affiliations than the first set, was absolutely critical in overcoming the Board’s obviousness rejection. The Board had found that the oral administration of 1-deamino-8-D-arginine vasopressin for gastrointestinal absorption was obvious in light of Vavra and the ‘491 patent. The sole purpose of the second set of declarations, therefore, was to show that the Vavra reference did not suggest that the peptide could be gastrointestinally absorbed. Towards this end, the declarations challenged the veracity of the Vavra reference and claimed that the reference was inapplicable to human gastrointestinal absorption. Not only were these declarations pivotal, they were essentially opinions that were supported largely by the declarants’ own scientific expertise and little else.

Second, we think it is equally clear that the summary judgment record shows that the past relationships were significant. Most significantly, one of the declarants, Robinson, was the research director at Ferring at the same time that Vilhardt was serving as a consultant to Ferring and was conducting his research on the very peptide at issue. Robinson was also a paid consultant for Ferring in the year immediately prior to his declaration. Czernichow was receiving research funding from Ferring at various points throughout the prosecution of the ‘398 patent and directly received funding before

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Affidavits are inherently material, even if only cumulative. The affirmative act of submitting an affidavit must be construed as being intended to be relied upon. It is not comparable to omitting an unnecessary act.” Refac, 81 F.3d at 1583 (emphasis added).

and after his 1986 declaration and continuing at least to the period immediately before his 1990 declaration. Finally, while Ferring may not have made payments to Barth personally, Ferring did fund Barth's research projects through Barth's employer. The privilege logs submitted by Ferring refer to all three of the declarants as "Ferring Consultants."<sup>10</sup>

These relationships were not isolated, nor were they confined to the distant past. The declarants clearly had ongoing and mutually beneficial relationships with Ferring during the prosecution of the '398 patent. In particular, Robinson's prior position as Ferring's research director and his subsequent consultant work for Ferring were extremely significant affiliations. The declarants were not disinterested. See Refac, 81 F.3d at 1581 (finding that "[i]t would surely have been important for the examiner, and any reasonable examiner, to know of Jones's [(the declarant)] association with Lanpar [(the inventor's company)]").

Despite appellants' assertions that the identity of the declarants was completely irrelevant to the examiners, the actual record made on summary judgment demonstrates otherwise. Indeed, it shows that the background, at least of the declarants Robinson and Czernichow, was not only material but was highly material.

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<sup>10</sup> Appellants argue that "Refac in fact held that, even after trial when credibility could be and was weighed, omitted disclosure of prior contacts that two PTO declarants [(Bullen and Cikra)] had had with the assignee of the patent in question did not suffice for materiality or intent, and did not constitute inequitable conduct." Ferring's Br. at 31. This is a misrepresentation of Refac's holding. There was no issue on appeal in Refac as to whether the omitted disclosure of the prior contacts of these two declarants was inequitable conduct. Our opinion simply described the district court's opinion. 81 F.3d at 1579. Even the district court's holding regarding these two declarants is not pertinent here because these declarants had no employment or financial connection with the inventors. Id.

The examiners specifically requested “non-inventor” affidavits. Moreover, the examiners expressly stated that they were concerned about the objectivity of those trying to distinguish the ‘491 patent from the ‘398 patent. In their 1986 rejection, the examiners stated: “As Applicants are the exclusive licensee of the Zaoral [‘491] patent, it is obviously expeditious for Applicants to argue that ‘peroral’ referred to in the patent referred only to sublingual or buccal routes, whereas the instant mode of administration [in their new patent] excludes such routes as it involves absorption by the gastrointestinal tract.” J.A. at 4390. The examiners were thus keenly aware of the fact that Ferring was the exclusive licensee of the ‘491 patent, which was soon to expire, and had an interest in convincing the PTO that the application described an invention not disclosed in the ‘491 patent. The examiners treated Ferring and the applicants as one and the same. Based on the examiners’ request for non-inventor affidavits and their subsequent comments, it is clear from the summary judgment record that the examiners were concerned about the objectivity of those providing declarations and their relationship to Ferring, and that they communicated this concern to the applicants.

Under such circumstances, the applicant is on notice as to the materiality of information regarding the declarants’ ties to Ferring. Of particular relevance here, we found in Refac that an examiner’s characterization of the inventor’s affidavit as “self-serving” put the inventors “on notice . . . that affidavits from disinterested persons were needed in order to overcome the substantive ground of the rejection.” Id. at 1581-82 (emphasis added). Here, on summary judgment the district court was correct to conclude as a matter of law that the examiners’ request for non-inventor declarations was for declarations from individuals without intimate ties to the inventors or Ferring

itself. The court could conclude from the record as a matter of law that this concern was pertinent to the further affidavits submitted following remand by the Board since the central concern was still the '491 patent as prior art whether alone or in combination with the Vavra reference.

Finally, on the issue of materiality, appellants argue that they could have, at trial, presented evidence to raise a fact issue concerning either the significance of the experts' views or the significance of the past relationships. But the appellants presented no such contrary evidence in response to the summary judgment motion. As we discuss below in connection with the issue of intent, the appellants cannot raise a genuine issue of material fact by speculating as to what evidence might have been introduced at trial.

Thus, the district court correctly determined that the undisputed facts established a threshold showing of materiality; indeed, the record established that the undisclosed information at least in the aggregate was highly material as a matter of law.

#### B. Intent

Even if an omission is found to be material, the omission must also be found to have been made with the intent to deceive. “[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.” GFI, Inc., 265 F.3d at 1274 (quoting Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 552 (Fed. Cir. 1990)). However, “[i]ntent need not, and rarely can, be proven by direct evidence.” Merck & Co., Inc. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1422 (Fed. Cir. 1989). We recently held in Bruno Indep. Living Aids, Inc. v. Acron Mobility Servs., Ltd., 394 F.3d 1348 (Fed. Cir. 2005), that “in the absence of a credible explanation,

intent to deceive is generally inferred from the facts and circumstances surrounding a knowing failure to disclose material information.” Id. at 1354 (emphasis added) (finding that where the patentee “has not proffered a credible explanation for the nondisclosure . . . an inference of deceptive intent may fairly be drawn in the absence of such an explanation”). Similarly, in Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253 (Fed. Cir. 1997), we made it clear that “a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish ‘subjective good faith’ sufficient to prevent the drawing of an inference of intent to mislead.” Id. at 1257.<sup>11</sup> Contrary to Ferring’s argument, the question of intent is directed to the applicant’s intent, not to the intent of the declarants. Thus, that the declarants may have had no intent to deceive is entirely irrelevant. The question is whether the applicant (here Vilhardt) had such an intent.

We need not in this case attempt to lay down a general rule as to when intent may be or must be inferred from the withholding of material information by an applicant. Suffice it to say that we have recognized, in cases such as Paragon, that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information and if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information; and (3) the applicant has not provided a credible

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<sup>11</sup> See also Warner-Lambert Co., 418 F.3d at 1346; Pharmacia, 417 F.3d at 1373; Semiconductor Energy Lab. Co. v. Samsung Elec. Co., 204 F.3d 1368, 1375 (Fed. Cir. 2000); cf. Dayco Prods., Inc., 329 F.3d at 1367 (“Intent to deceive cannot be inferred simply from the decision to withhold the reference where the reasons given for the withholding are plausible.”).

explanation for the withholding. See Bruno Indep. Living Aids, 394 F.3d at 1354; Critikon, Inc., 120 F.3d at 1257. Here, all three conditions are satisfied.

First, Barr established that Vilhardt knew of significant past relationships of at least two of the declarants. Vilhardt was aware that Robinson was Ferring's pre-clinical research director while Vilhardt was serving as a consultant to Ferring researching the very peptide at issue. Robinson served as Vilhardt's contact at Ferring during this time. Vilhardt was also aware of Bath's affiliation with Ferring. Although he testified that he did not believe that Barth was a Ferring "consultant," he indicated that he was aware of a working arrangement between Ferring and Barth's employer under which Ferring had funded support for Barth's research. Additionally, as Ferring notes in its brief, "[b]etween 1988 and 2000, [Barth] worked a month most years in Dr. Vilhardt's laboratory for which he was paid a maintenance stipend." Ferring's Br. at 28.<sup>12</sup>

As to the second question—Vilhardt's knowledge of the materiality of the information—it is undisputed that the examiners were concerned about the identity of the affiants and that Vilhardt was aware of this concern since he was present at the interview with the examiners when the concern was expressed. A similar factual scenario supported a finding of intent in Refac, 81 F.3d at 1580. There, the examiner indicated that an affidavit by the co-inventor on a particular issue was "self-serving." We concluded that "[g]iven what the examiner characterized as the self-serving nature of [the inventor's] affidavit, [the applicants] were on notice from the PTO that affidavits from disinterested persons were needed in order to overcome the substantive ground of the rejection." Id. at 1581-82 (emphasis added). We then upheld a finding of intent

to mislead the PTO. Id. Similarly, the fact that the examiners here requested “non-inventor” affidavits and expressed concern about bias supports the district court’s conclusion that Vilhardt was on notice that disinterested affidavits were necessary, and knew or should have known that the Ferring affiliations were material.

Finally, the appellants urge that there is potentially a credible explanation here for the withholding. The crux of appellants’ argument is that there are possible benign explanations for the withholding and that evidence might have been developed at trial to support those theories. Thus, appellants assert that it was improper for the district court to grant summary judgment to Barr “without seeing or hearing from the accused Dr. Vilhardt,” Aventis’ Br. at 34, and complained that “Barr’s counsel did not ask Dr. Vilhardt or any other declarant a single question which would bear on the issue of intent.” Ferring’s Br. at 30. We find this argument to be quite remarkable. On summary judgment, in order to create a genuine issue, the appellants bore the burden of submitting an affidavit from Vilhardt to contradict the movant’s evidence of intent if they believed that testimony from Vilhardt would establish credible evidence for the withholding.<sup>13</sup> Appellants cannot create a genuine issue by suggesting that Vilhardt might have proffered favorable evidence at trial. As we said in Paragon, when the movant has “made a prima facie case of inequitable conduct by satisfying both

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<sup>12</sup> The record is unclear as to whether Vilhardt was aware of Czernichow’s longstanding relationship with Ferring.

<sup>13</sup> Appellants argue that the district court improperly made credibility findings concerning Vilhardt on summary judgment. Typerright Keyboard Corp. v. Microsoft Corp., 374 F.3d 1151, 1158 (Fed. Cir. 2004) (holding that in some circumstances, summary judgment may be inappropriate when the credibility of an affiant is drawn into question). Here however, appellants’ argument is misplaced because Vilhardt’s credibility was never in dispute. Credibility can only become an issue once a party offers a declarant’s testimony in support or in opposition to summary judgment.

elements thereof, the burden shift[s] to [the nonmovant] to come forward with evidence which would require reassessment of the validity of the defense.” 984 F.2d at 1191.

Appellants’ specific arguments fare no better. Appellants argue that Vilhardt, as a foreign scientist, was not familiar with patent prosecution, and therefore would not have known of “some obligation to disclose declarants’ associations with Ferring.” Aventis’ Br. at 28. There is no record evidence supporting Vilhardt’s lack of knowledge.<sup>14</sup> To the contrary, the summary judgment record compels the conclusion that Vilhardt was aware of his obligations. In executing his inventorship declaration, Vilhardt acknowledged his “duty to disclose information which is material to the examination of this application.” J.A. 3455. Furthermore, Vilhardt was represented by counsel throughout the proceedings before the PTO.

Appellants also argue that “there was no reason for Dr. Vilhardt, a foreigner and non-lawyer, to have understood the examiner to be requesting declarations from persons with no relationship to Ferring.” Aventis’ Br. at 25. Here again, appellants offered nothing to support such an inference. As we have already discussed in Refac, once the examiner discounts an affidavit for bias, the applicant is deemed to be on notice that a disinterested affidavit is required. 81 F.3d at 1581-82. The evidence here indicates that the examiners previously discounted the opinions of those connected to Ferring because the examiners found Ferring to have a substantial interest in the patent. Given the examiners’ statements and the evidence that Vilhardt understood

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<sup>14</sup> The situation here is quite different from that in In re Harita, 847 F.2d 801 (Fed. Cir. 1988), where the charge of intent to mislead was refuted by detailed explanations of the failure to disclose prior art by a Japanese patent agent unfamiliar with United States patent requirements.

their request and played more than a bystander's role in obtaining the affidavits, one cannot reasonably infer that Vihardt was simply unaware of the examiners' concerns or his duty to satisfy those concerns.

In short, appellants' argument concerning credible explanations consists entirely of speculation. Conclusory allegations and attorney arguments are insufficient to overcome a motion for summary judgment. Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc., 249 F.3d 1341, 1353 (Fed. Cir. 2001); Glaverbel Societe Anonyme v. Northlake Marketing & Supply, Inc., 45 F.3d 1550, 1562 (Fed. Cir. 1995) ("There must be sufficient substance, other than attorney argument, to show that the issue requires trial."). As we said in Paragon, "insupportable, [or] specious . . . explanations or excuses will not suffice to raise a genuine issue of fact." 984 F.2d at 1190. In order to raise a genuine issue of fact, a party must submit conflicting evidence in the form of an affidavit or other admissible evidence.<sup>15</sup>

Far from there being a credible explanation for the withholding, there is evidence in the summary judgment record supporting a conclusion that the past relationships were deliberately concealed. Although Vilhardt (who was already known by the examiners to have an affiliation with Ferring) submitted a CV with his declaration which

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<sup>15</sup> Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248-49 (1986) (holding that once the movant properly supports its motion for summary judgment, the burden of production shifts to the nonmovant and it "may not rest upon the mere allegations or denials of [its] pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial") (internal quotation marks omitted); Biocorp, Inc., 249 F.3d at 1353 ("The party opposing the [summary judgment] motion must point to an evidentiary conflict created on the record at least by a counter statement of a fact or facts set forth in detail in an affidavit by a knowledgeable affiant. Mere denials or conclusory statements are insufficient.") (quoting Barnag Barmer Maschinenfabrik AG v. Mach. Ltd., 731 F.2d 831, 836 (Fed. Cir. 1984)).

disclosed that he had previously been the Research Director at Ferring, Robinson's declaration came with no CV and no indication that he was recently Ferring's Research Director. Likewise, Barth's declaration was submitted with no CV. Unlike the others, Czernichow's declaration was accompanied by an extensive CV. However, it failed to mention his research funding from Ferring. Under similar circumstances, we concluded that the omission of prior employment with the patentee supported a showing of intent. See Refac, 81 F.3d at 1581. So too Vilhardt initially stated that he had no contact with the declarants, but later admitted—when confronted with the privilege log referring to these individuals as Ferring consultants—that he had contacted each of the declarants and that he sent Barth and Robinson “draft declarations,”<sup>16</sup> thus suggesting a desire to conceal the extent of his involvement.

We conclude that the district court properly granted summary judgment on the issue of intent.

## II

Having found that there were no genuine factual disputes with respect to the issues of materiality and intent, we turn to the question whether the court properly weighed materiality together with intent to determine that the conduct was “inequitable.” We review the district court's ultimate finding of inequitable conduct for abuse of discretion. See Kingsdown Med. Consultants, Ltd. v. Hollister Inc., 863 F.2d 867, 876 (Fed. Cir. 1988); Paragon, 984 F.2d at 1191. The same standard applies to review of

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<sup>16</sup> Barr's evidence that Vilhardt was involved in the drafting of the declarations consists of Vilhardt's own deposition testimony that he sent “draft declarations” to both Barth and Robinson, as well as statements by Czernichow and Barth indicating that they did not write all parts of their declarations.

discretionary determinations where the district court rules on summary judgment. See Gen. Elec. Co. v. Joiner, 522 U.S. 142-43 (1997) (holding that the district court's exclusion of expert testimony made in the context of a summary judgment motion was reviewed for abuse of discretion while the existence of separate issues of fact were reviewed de novo).<sup>17</sup>

In evaluating the conduct here, we note again that the omitted affiliation with respect to Robinson in particular was highly material since Robinson had actually been employed by Ferring. So too there was not simply a single omission. Rather, there were multiple omissions over a long period of time—a fact that heightens the seriousness of the conduct. See Refac, 81 F.3d at 1580, 1582 (finding that additional omissions, even if they do not themselves constitute inequitable conduct, can heighten the effect of the omission at issue). Here, by presenting five separate declarations to the examiners, the applicants appeared to have a broad consensus of scientific support to overcome the Vavra reference. In actuality, four of the five declarations were submitted by scientists with significant associations with the assignee itself. While we will never know how the examiners may have weighed the declarations differently, it seems clear to us that this stellar showing of support would have, at the very least, been

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<sup>17</sup> See, e.g., Scholle Corp. v. Blackhawk Molding Co., Inc., 133 F.3d 1469, 1471 (Fed. Cir. 1998) (reviewing a district court's finding of equitable estoppel on summary judgment for abuse of discretion); Alternative Sys. Concepts, Inc. v. Synopsys, Inc., 374 F.3d 23, 31 (1st Cir. 2004) (reviewing a district court's finding of judicial estoppel on summary judgment for abuse of discretion); Nat'l Ass'n of Gov't Employees v. City Pub. Serv. Bd., 40 F.3d 698, 707 (5th Cir. 1994) (reviewing a district court's finding of laches on summary judgment for abuse of discretion); Booth v. Barber Transp. Co., 256 F.2d 927, 931 (8th Cir. 1958) (reviewing a district court's grant of specific performance on summary judgment for abuse of discretion).

tarnished. In view of all the circumstances, we cannot find that the district court abused its discretion in finding inequitable conduct.

In coming to this conclusion, we fully recognize that inventors often consult their colleagues or other persons skilled in the art whom they have met during the course of their professional life. Accordingly, when an inventor is asked to provide supportive declarations to the PTO, it may be completely natural for the inventor to recommend, and even contact, his own colleagues or people who are, or who have been, affiliated with his employer and to submit declarations from such people. Nothing in this opinion should be read as discouraging such practice. Rather, at least where the objectivity of the declarant is an issue in the prosecution, the inventor must disclose the known relationships and affiliations of the declarants so that those interests can be considered in weighing the declarations. This is not an onerous burden to place on any applicant.

#### CONCLUSION

For the foregoing reasons, the decision below is affirmed.

AFFIRMED

COSTS

No costs.

# United States Court of Appeals for the Federal Circuit

05-1284

FERRING B.V.,

Plaintiff-Appellant,

and

AVENTIS PHARMACEUTICALS, INC.,

Plaintiff-Appellant,

v.

BARR LABORATORIES, INC.,

Defendant-Appellee.

NEWMAN, Circuit Judge, dissenting.

"Inequitable conduct" in patent practice means misconduct by the patent applicant in dealings with the patent examiner, whereby the applicant or its attorney is found to have engaged in practices intended to deceive or mislead the examiner into granting the patent. It is a serious charge, and the effect is that an otherwise valid and invariably valuable patent is rendered unenforceable, for the charge arises only as a defense to patent infringement.

As this litigation-driven issue evolved, the law came to demand a perfection that few could attain in the complexities of patent practice. The result was not simply the elimination of fraudulently obtained patents, when such situations existed. The consequences were

disproportionally pernicious, for they went far beyond punishing improper practice. The defense was grossly misused, and with inequitable conduct charged in almost every case in litigation, judges came to believe that every inventor and every patent attorney wallowed in sharp practice. This history was recently summarized as follows:

As is known, about 20 years ago inequitable conduct was frequently pleaded as a defense to patent infringement; a patent that is "unenforceable" due to a finding of inequitable conduct is dead. The defense was so misused by alleged infringers that the Federal Circuit once called this defense a "scourge" on US patent litigation . . . . The famous Kingsdown seemed to put a stop to the defense of inequitable conduct. . . .

Michael D. Kaminski, Effective Management of US Patent Litigation, 18 Intell. Prop. & Tech. L.J. 13, 24 (2006) (footnote omitted) (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867 (Fed. Cir. 1988) (*en banc* in relevant part)).

My colleagues on this panel have regressed to that benighted era, rejecting the efforts of Kingsdown to bring objectivity to charges of inequitable conduct, instead reviving the culture of attack on inventor rights and attorney reputations based on inference and innuendo. My colleagues, endorsing several novel and unsupportable presumptions of wrongdoing, do injury to the reasonable practice of patent solicitation, even as they defy the rules of summary judgment.

This is not hyperbole. Practitioners from an earlier era well recall the adverse impact on industrial innovation when patents were not a reliable support for commercial investment, based in part on the judicial belief that patents and their practice were seriously flawed. With invalidation of most of the patents that reached the courthouse, the contribution of a diminished patent incentive to the weakening of technology-based investment was a serious national concern, and the impact on the nation's commercial

vigor was recognized by government as well as by the industrial and scientific communities. See Domestic Policy Review of Industrial Innovation, Final Report, Dep't of Commerce (1979). The formation of the Federal Circuit Court of Appeals was part of the nation's program to restore technology-based leadership with the aid of an effective patent system.

The Federal Circuit recognized that specious charges of inequitable conduct were a disincentive to technologic innovation, and in Burlington Indus. v. Dayco Corp., 849 F.2d 1418, 1422 (Fed. Cir. 1988) this court remarked that "the habit of charging inequitable conduct in almost every major patent case has become an absolute plague." The Federal Circuit understood the ease with which accused infringers could challenge the niceties of patent prosecution, for as the law stood it was irrelevant whether the examiner was in fact deceived, or whether the purported flaw in prosecution affected patentability, or whether the action was an intentional misrepresentation or at worst negligence, or whether the invention met the statutory requirements of patentability.<sup>1</sup> Thus the Federal Circuit undertook to bring objective standards and reasoned perspective to the charge of inequitable conduct.

In Kingsdown, the Federal Circuit held that in order to invalidate a patent for inequitable conduct in obtaining the patent, there must be both a material misrepresentation

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<sup>1</sup> For example, an inventor is required to provide the Patent Office with all prior art references known to the inventor that are "material to patentability"; if the inventor provided selected references, he was accused of inequitable conduct in the selection; and if he provided an entire search report, he was accused of burying the significant references. The inventor was also required to provide a one-sentence statement about each reference that he listed; much was made of whatever was and was not in that sentence.

and intent to deceive. The court established that it is necessary to consider all of the evidence including evidence of good faith, and that both materiality and deceptive intent must be proved by clear and convincing evidence. Kingsdown established that no longer would negligence alone support a holding of inequitable conduct. The Federal Circuit did not believe that inventors and patent attorneys are more or less virtuous than anyone else; they simply held that charges of deceptive action must be proved on objective standards, as the law requires for property-forfeiting charges under the common law. Experience shows that Kingsdown's simple changes in the law were an important contribution to restoration of the patent system as an incentive to industrial innovation, for this court has recognized that a "patentee's oversights are easily magnified out of proportion by one accused of infringement." Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 939 (Fed. Cir. 1990) (quoting Pfizer, Inc. v. Int'l Rectifier Corp., 538 F.2d 180, 186 (8th Cir. 1976)).

Today my colleagues on this panel not only ignore Kingsdown and restore a casually subjective standard, they also impose a positive inference of wrongdoing, replacing the need for evidence with a "should have known" standard of materiality, from which deceptive intent is inferred, even in the total absence of evidence. Thus the panel majority infers material misrepresentation, infers malevolent intent, presumes inequitable conduct, and wipes out a valuable property right, all on summary judgment, on the theory that the inventor "should have known" that something might be deemed material. The panel majority, steeped in adverse inferences, holds that good faith is irrelevant and presumes bad faith. Thus the court resurrects the plague of the past, ignoring the Kingsdown requirements of clear and convincing evidence of a misrepresentation or omission material

to patentability, made intentionally and for the purpose of deception. I respectfully, but urgently, dissent.

### ***The Accused Conduct***

The examiner, at an interview at which the inventor Dr. Vilhardt was present, asked for "non-inventor" affidavits on the meaning of "peroral" and its significance to the claimed invention, apparently in accordance with the PTO custom that an inventor's statements are not adequate.<sup>2</sup> The inventor strictly complied with this request, presenting statements of four distinguished scientists who were not inventors. The filing of the declarations of three of the affiants, Drs. Czernichow, Robinson, and Barth, is held by my colleagues to establish inequitable conduct simply because they did not state their past professional relationships with the applicant. These past affiliations are not clearly and convincingly material as a matter of law, and their omission does not establish clear and convincing evidence of deceptive intent as a matter of law.

Dr. Paul Czernichow was a world renowned pediatric endocrinologist, Professor of Pediatrics at the Hospital des Enfants-Malades, Paris, and had published 106 papers. The record states that Ferring had provided equipment used in a clinical trial that Dr. Czernichow had previously conducted at the hospital. He received no remuneration from Ferring for this trial, and was not paid for his affidavit. Although the majority makes much of his "extensive CV" that fails to mention the funding for the clinical trial, the majority fails to

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<sup>2</sup> An examiner later dismissed the requested declarations defining "peroral," stating that "such evidence is not necessary to construe the meaning of an ordinary term in the English language."

point out that 25 of the 28 pages of his CV list his publications, and the first 3 pages -- where his qualifications, work experience and honors are listed -- are organized such that one would not expect partial funding for a research project to appear. The most reasonable inference, to which Ferring is entitled on summary judgment, is that Dr. Czernichow's relationship with Ferring was so remote as to not be worthy of a listing in his CV. Further, as my colleagues acknowledge, the summary judgment record contains no evidence that Dr. Vilhardt was aware of this prior relationship. Indeed, the only evidence on this issue is his answer upon being asked whether he knew whether Dr. Czernichow had been a Ferring consultant: "Not to my knowledge, no, but whether he had some kind of grant from Ferring I wouldn't know, but I never heard him described as a consultant."

Dr. Tomislav Barth was a Professor at the Academy of Sciences of the Czech Republic in the Department of Organic Chemistry and Biochemistry, with twenty-five years of experience in the fields of peptide biochemistry, metabolism, pharmacology and pharmacokinetics. The record states that Ferring had made research grants to the Czech Academy of Sciences, and that Dr. Barth worked on such projects, although he was not compensated by Ferring. Dr. Barth later did some experimental work for Ferring for "allowances and accommodation and costs," but he was not engaged in such work at the time of his declaration and was not paid for his affidavit. There is no evidence in the summary judgment record that Dr. Vilhardt was aware of this prior affiliation, apart from his speculation during questioning that "it is possible that Tomislav Barth, who was a sort of contact person between Ferring and the department - the academy, that he may have obtained a small fee for that. I don't know."

Dr. Myron Miller was the Chief of Geriatric Medicine at the Veterans Administration Medical Center in Syracuse, New York, and had published 111 scientific papers. The record shows no research or employment relationship with the applicant, and none is asserted. Dr. Miller submitted two declarations, one to define "peroral" and one concerning gastrointestinal absorption. He was not paid for these statements.

Dr. I.C.A.F. Robinson, a neurophysiologist and an expert in neurophysin chemistry, was at the time of his declaration the head of the Division of Molecular Neuroendocrinology at the National Institute for Medical Research in London; he held a doctorate in endocrinology from Oxford University and had published 161 scientific papers. Dr. Robinson worked for Ferring as director of pre-clinical research for one year from 1985-86, and as a paid occasional consultant until 1989. He too was not paid for his statements, and by the time of his 1990 declaration, his consulting relationship with Ferring had ended. His declaration was not submitted in response to the examiner's request for "non-inventor" testimony in 1986; it was filed four years later, after the Board had affirmed the applicant's interpretation of "peroral" and entered a new rejection based on obviousness.

In short, the summary judgment record consists of declarations by four respected non-inventor scientists, three of whom had a scientific relationship with Ferring, and Dr. Vilhardt knew of only one of these affiliations -- Dr. Robinson's affiliation that was omitted from a declaration submitted after the relationship ended and four years after the examiner's request for "non-inventor" testimony. There is no evidence, or even an allegation, that any of these scientists had anything to gain or lose as a result of the issuance of the '398 patent. The finding of the panel majority that all of the affiants had "intimate ties" with the patentee is a mischaracterization, and the inference that their

scientific opinions may be biased and were submitted with deceptive intent is a travesty. Further, such a charge of malfeasance cannot be decided adversely on summary judgment. See generally IV Wigmore on Evidence §1104 (3d ed. 1957) (every witness is in law assumed to be of normal moral character for veracity). There is simply no evidence of any intention to withhold these relationships; in fact, there is no evidence that Dr. Vilhardt even thought about whether or not to disclose these affiliations, much less that he made the deliberate decision to withhold material information from the PTO. Indeed, the professors' reputations are enough, on the face of their scholarship, to put into dispute the panel majority's summary judgment that they deliberately concealed information that was important to the credibility of their affidavits.

Nonetheless, my colleagues, without inquiry or evidence, rule that deceptive intent must be inferred. The panel majority posits that the examiner was necessarily misled, and intentionally so, by the absence from their affidavits or curricula vitae of these relationships.

The majority reaches this conclusion that clear and convincing evidence of materiality and intent are established, not upon considering and weighing the particular facts, but by adverse inference and presumption, on summary judgment. That is not the law of inequitable conduct, and it is not a reasonable application of any of the rules and protocols of evidence. See Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1566 (Fed. Cir. 1987) ("If facts of materiality or intent are reasonably disputed, the issue is not amenable to summary disposition.")

### ***Materiality***

The issue here is not patent validity. The panel majority's finding of "materiality" is not substantive scientific materiality, but materiality per se of the relationship of the affiant to the applicant. There is no evidence or assertion that any of the affiants mis-defined "peroral" or presented a false opinion, or that the examiner was deceived by the information provided or not provided, or that these scientists provided misinformation or deliberate omissions in order to deceive the examiner. There is no evidence that the examiner, in asking for the views of "a non-inventor," was asking for or expecting the views of a stranger to the applicant.

The panel majority places great weight on the cases of Paragon Podiatry and Refac, where, on quite different facts, the court found deliberate misrepresentation of the relationship of an affiant for deceptive purposes. These cases do not support the sweeping inference now applied. In Paragon Podiatry Lab., Inc. v. KLM Labs., Inc., 984 F.2d 1182, 1188 (Fed. Cir. 1993), materiality was not even at issue, the appellants having conceded that the examiner's request for a "disinterested third party" was not met by declarations from former consultants owning stock in the assignee's company. The affiants in Paragon not only failed to mention their stock ownership, but made the carefully worded statement that they were not "in the past employed by nor do I intend in the future to be employed by" the patentee. Id. at 1191. The court agreed that this "half-truth" was a material representation affecting the substantive content of the affidavits, and a deliberately artful contravention of the examiner's requirement. Id. at 1192. And in Refac International, Ltd. v. Lotus Development Corp., 81 F.3d 1576, 1579 (Fed. Cir. 1996) the relevant omitted material information was the declarant's prior experience with the invention. The declarant in Refac stated that "he could have written" the claimed computer program "from the written

disclosures and flow chart shown in the drawing of [the] patent application," but failed to disclose that he "had worked with and reviewed documentation for the commercial embodiment of the invention" as an employee at the inventor's company, and had "recognized the flow chart as being essentially the same one" shown to him during training at the company. Id. at 1581. In Refac the Federal Circuit upheld the ruling of inequitable conduct, but also cautioned that finding "the omission of an aspect of one's employment history to be inequitable conduct might thus seem to be unduly severe, a heavy penalty for an arguably minor omission." Id. at 1584.

The panel majority misreads these cases as holding that prior employment history is always material if (1) the declarant's testimony is material and (2) the prior affiliation is "significant." Given the minimal affiliations found "significant" in this case, and the majority's holding that affidavits are always material, under the majority's rule the negligent omission of a past affiliation with an applicant will always be inequitable conduct. Neither Paragon nor Refac supports a broad rule that past affiliations are always material, whatever those affiliations and whatever their relation to the subject matter. To the contrary, these cases were analyzed and findings made in accordance with the Kingsdown criteria. Materiality requires evidence, as does deceptive intent. The panel majority's new per se rule is contrary to precedent, contrary to the rules of evidence, and contrary to reason, as is its assertion that the omitted relationships in this case are "highly material." See Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1367 (Fed. Cir. 2003) ("This court has held that affirmative misrepresentations by the patentee, in contrast to misleading omissions, are more likely to be regarded as material.")

Paragon and Refac, like all precedent in this area, illustrate that questions of materiality and intent are factual in nature, and that per se inferences of bad faith and deception are improper. In Juicy Whip, Inc. v. Orange Bang, Inc., 292 F.3d 728 (Fed. Cir. 2002) this court agreed that the employment relationship of the declarant was not material to patentability, even though the applicant knew that the examiner had misunderstood the declaration as indicating that the declarant worked for a competitor. In Juicy Whip, as in Refac and Paragon, the court considered the particular facts with respect to both materiality and intent. In Refac, 81 F.3d at 1579, inequitable conduct was found in the declarant's concealed prior experience with the invention, for his declaration stated that he "could have written" the claimed computer program from the specification alone. In Juicy Whip, in contrast, the misunderstood employment relationship was held by this court not to be material "to the issue before the examiner." 292 F.3d at 744. The panel majority errs in characterizing Juicy Whip as holding that "the substance of an affidavit may be immaterial where the facts asserted therein were undisputed," maj. op. at 12 n.8, for that was not the issue. Indeed, the court was "bothered" by the applicant's failure to correct the examiner's misunderstanding of the affiant's relationship, but concluded that this aspect was "immaterial to the issue before the examiner." 292 F.3d at 744.

Whether a past relationship between a declarant and the patent applicant is material to patentability depends on the facts of the relationship and the nature of the declaration. It is not per se material; and failure to explain the relationship is not per se deception. Indeed, it is rare that any scientist working in a specialized field would not have interacted professionally with other scientists and with the industries in that field. Such relationships do not warrant an inference of bias and deception. There must be evidence and analysis,

not innuendo. Scientific integrity should not be impeached by per se rules without foundation.

On the facts of this case, where the declarants provided a text-book definition of "peroral" and their scientific opinion of the gastrointestinal behavior of the product, the past connections of these declarants do not establish per se material misrepresentation. "Information is material if a reasonable examiner would have considered it important to the patentability of a claim." Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1570, 1571 (Fed. Cir. 1997) ("[U]nfounded speculation is not clear and convincing evidence of materiality.") The information in these affidavits was not shown to be incorrect. See Regents, 119 F.3d at 1570 ("There is no reason to believe that a reasonable examiner would have made any different decision . . . ."). The fundamentals of due process should not and cannot be replaced by non-evidentiary inferences and unfounded speculation.

### ***Intent***

In cases involving an omission of material information, "there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known material reference." Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998); see Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1574 (Fed. Cir. 1991) ("Conduct that requires forfeiture of all patent rights must be deliberate, and proved by clear and convincing evidence.") Thus, to prevail on summary judgment, Barr must establish that no reasonable jury could fail to find clear and convincing evidence of deceptive intent. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255-56 (1986).

In its motion for summary judgment, Barr put forward no evidence of deceptive intent. Nonetheless, the majority holds that clear and convincing evidence of deceptive intent may be inferred on summary judgment where the record establishes that the applicant "knew or should have known" that omitted information was material. The majority's ruling is directly contrary to Kingsdown, which held that even gross negligence may not establish deceptive intent, and that "the involved conduct, viewed in light of all the evidence, including evidence indicative of good faith, must indicate sufficient culpability to require a finding of intent to deceive." 863 F.2d at 876; see Hewlett-Packard Co. v. Bausch & Lomb, Inc., 882 F.2d 1556, 1562 (Fed. Cir. 1989) ("[G]rossly negligent conduct may or may not compel an inference of an intent to mislead. Such an inference depends upon the totality of the circumstances . . . .") Of course, dishonest persons rarely confess to malfeasance, but the court goes too far in establishing such deceptive intent as a matter of law based on inference as to what an inventor "should have known." See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1181 (Fed. Cir. 1995) ("the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed . . . . In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference").

The majority cites Bruno Indep. Living Aids and Critikon, Inc. to supports its proposition that the court has recognized

in cases such as Paragon, that summary judgment is appropriate on the issue of intent if there has been a failure to supply highly material information if the summary judgment record establishes that (1) the applicant knew of the information; (2) the applicant knew or should have known of the materiality of the information, and (3) the applicant has not provided a credible explanation

for the withholding. See Bruno Indep. Living Aids, 394 F.3d at 1354; Critikon, Inc., 120 F.3d at 1257.

Maj. op. at 17-18. That is an inaccurate summary of precedent. Paragon involved an affirmative misrepresentation, not an omission, and that case contains no suggestion of a "should have known" standard of materiality. See Paragon, 984 F.2d at 1192 (deceptive intent was established on summary judgment because the record only led to one conclusion upon considering all of the circumstances, including the fact that there was a "submission of deceptive, if not outright false, affidavits to the PTO"). And the court in Bruno Independent Living Aids, Inc. v. Acorn Mobility Servs. Ltd., 394 F.3d 1348 (Fed. Cir. 2005) did not grant summary judgment, but rather affirmed a district court's findings of deceptive intent on a standard of clear error, noting the high materiality of the omitted reference and the other particular facts of the case. The court's statement in Bruno Indep. Living Aids that "an applicant who knew of the art or information cannot intentionally avoid learning of its materiality . . . it may be found that the applicant 'should have known' of that materiality," 394 F.3d at 1352 (quoting FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1415 (Fed. Cir. 1987)), does not apply in this case, for there is no evidence or argument that Dr. Vilhardt deliberately avoided learning of the materiality of the undisclosed contacts. A fact-finder could not find that the applicant had knowledge of materiality, upon consideration of all the circumstances of record.

Nor was there a mere failure to disclose a known material reference in Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997); the applicant in Critikon, Inc. also knowingly failed to disclose in reissue proceedings that invalidity and inequitable conduct were simultaneously being asserted as defenses in

litigation involving the very same patent. Id. at 1255. And although the court stated that "intent may be inferred where a patent applicant knew, or should have known, that withheld information would be material to the PTO's consideration of the patent application," id. at 1256, this proposition was supported solely by reference to Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984), a case that was overruled *en banc* by Kingsdown on this very point. See Kingsdown, 863 F.2d at 876. Thus, this aspect of Critikon, Inc. has been correctly identified by practitioners as "bad law," both because it relies on the overruled Driscoll decision and because it is representative of a recent resurgence of the plague that Kingsdown had intended to cure.<sup>3</sup> See Lynn C. Tyler, Kingsdown Fifteen Years Later: What Does It Take to Prove Inequitable Conduct?, 13 Fed. Cir. B.J. 267, 276-78 (2004) (discussing the resurgence of Federal Circuit panel decisions that rely on precedent explicitly overruled by Kingsdown). Further, there is a wide gulf between a rule that intent "may" be inferred by a jury upon consideration of all the circumstances, in accordance with Kingsdown, and a rule that intent "must" be inferred as a matter of law against a party opposing summary judgment, based solely on a material omission, in violation of Kingsdown and in violation of the rules of summary judgment.

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<sup>3</sup> Indeed, the panel majority's citation to Digital Control Inc. v. Charles Mach. Works, \_\_\_ F.3d at \_\_\_, 2006 U.S. App. LEXIS 2991, slip op. at 7-12 (Fed. Cir. Feb. 8, 2006) is a further indication of the court's departure from precedent concerning inequitable conduct. The court in Digital Control holds, in contradiction of precedent, that it will hold practitioners to the standard of the pre-1992 version of Rule 56 for patents prosecuted after 1992, even though that standard no longer exists. 2006 U.S. App. LEXIS 2991, at \*10-19.

Although some recent panel decisions appear to have relied on precedent overruled by Kingsdown, such decisions cannot overrule an *en banc* decision of this court, or the numerous post-Kingsdown cases that have held fast to the requirement of clear and convincing evidence of both materiality and intent. See, e.g., Hoffmann-La Roche, 323 F.3d at 1361 ("the district court committed clear error in finding clear and convincing evidence of intent to deceive in the inventors' failure to disclose"); Allen Eng'g Corp. v. Bartell Indus., 299 F.3d 1336, 1351 (Fed. Cir. 2002) (rejecting argument that nondisclosed information was so material that its nondisclosure should infer an intent to deceive, "for even if [the applicant's] conduct amounted to gross negligence, this alone would not be sufficient to show the requisite intent"); Catalina Lighting, Inc. v. Lamps Plus, Inc., 295 F.3d 1277, 1289 (Fed. Cir. 2002) ("intent to deceive can not be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent") (quoting Hebert v. Lisle Corp., 99 F.3d 1109, 1116 (Fed. Cir. 1996)); Jazz Photo Corp. v. Int'l Trade Comm'n, 264 F.3d 1094, 1110 (Fed. Cir. 2001) ("absence of a reference from the prosecution record does not prove deceptive intent; there must be evidence sufficient to show, clearly and convincingly, the intent to withhold material information in order to deceive or mislead the examiner"); Molins, 48 F.3d at 1181 ("the alleged conduct must not amount merely to the improper performance of, or omission of, an act one ought to have performed. Rather, clear and convincing evidence must prove that an applicant had the specific intent to accomplish an act that the applicant ought not to have performed, viz., misleading or deceiving the PTO"); Therma-Tru Corp. v. Peachtree Doors Inc., 44 F.3d 988, 996 (Fed. Cir. 1995) (intent to deceive or mislead should not be inferred from the fact that information was not provided to the examiner); Halliburton Co. v. Schlumberger Tech.

Corp., 925 F.2d 1435, 1443 (Fed. Cir. 1991) ("As Kingsdown made abundantly clear, gross negligence alone does not compel the inference of intent to deceive. Gross negligence cannot elevate itself by its figurative boot-straps to an intent to mislead based on the identical factors used to establish gross negligence in the first instance unless all the facts and circumstances indicate sufficient culpability."); Allen Organ Co. v. Kimball Int'l, Inc., 839 F.2d 1556, 1567 (Fed. Cir. 1988) ("[M]ateriality does not presume intent, which is a separate and essential component of inequitable conduct.")

Numerous cases affirm the principle that inequitable conduct requires consideration of the record as a whole, including evidence of good faith. See, e.g., Warner-Lambert Co. v. Teva Pharms. USA, Inc., 418 F.3d 1326, 1348 (Fed. Cir. 2005) ("there is no bright line test for determining whether inequitable conduct occurred; each case must be assessed independently"); Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1383 (Fed. Cir. 2000) ("Under all the circumstances of record, the court did not seriously misjudge the import of the evidence . . . in reaching the conclusion that equity warranted rendering the patent unenforceable."); Upjohn Co. v. MOVA Pharm. Corp., 225 F.3d 1306, 1312 (Fed. Cir. 2000) ("Both materiality and intent to deceive must be proven by clear and convincing evidence."); Refac, 81 F.3d at 1584-85 (recognizing the importance of credibility findings in evaluating intent).

Heretofore, no case has found inequitable conduct based on omitted information when there was no evidence of intentional omission and not even circumstantial evidence of deceptive intent. The panel majority's holding that deceptive intent is established as a matter of law if the applicant "should have known" that information might be material to

patentability, further revives the "plague" of the past, with burdens that far outweigh any conceivable benefits.

### ***Summary Judgment***

The court not only creates a new rule of law, but faults the patentee for failing to provide, on the summary judgment record, evidence to respond to an unknown "should have known" per se rule that until now was absent from this law. It is improper, and unfair, to require nugatory evidence on a point that was not raised in the motion for summary judgment, and then to grant the motion because the balancing evidence was not there. The panel majority not only charges the inventor Dr. Vilhardt with at least negligence, but denies him the opportunity now to respond to the court's creative new ruling. Although in Therma-Tru Corp., 44 F.3d at 996, this court stated that the "theory of inferential culpability was definitively laid to rest in Kingsdown," if it is to be revived the inventor must be given the opportunity to support his good faith.

In Poller v. Columbia Broadcasting System, Inc., 368 U.S. 464 (1962), the Court cautioned against the grant of summary judgment when "motive and intent play leading roles," for:

It is only when the witnesses are present and subject to cross-examination that their credibility and the weight to be given their testimony can be appraised. Trial by affidavit is no substitute for trial by jury which so long has been the hallmark of "even handed justice."

368 U.S. at 473. This court has often held similarly, for intent to deceive is a question of "the state of mind of one making representations," Kangaroos U.S.A., Inc., v. Caldor, Inc., 778 F.2d 1571, 1576 (Fed. Cir. 1985), a "factual matter rarely free from dispute," id. at 1577, and thus "rarely enabled in summary proceedings." Id.; see Monsanto Co. v. Bayer

Bioscience N.V., 363 F.3d 1235, 1241 (Fed. Cir. 2004) ("It was therefore improper for the district court on summary judgment to infer an intent to deceive based on the court's conclusion that the declaration was false and that the explanation for the falsity was unpersuasive."); Copelands' Enters., Inc. v. CNV, Inc., 945 F.2d 1563, 1567 (Fed. Cir. 1991) ("As a general rule, the factual question of intent is particularly unsuited to disposition on summary judgment.")

For summary judgment of inequitable conduct there must be clear and convincing evidence of materiality and deceptive intent, even on the non-movant's view of the facts. In this case, credibility has been placed at issue. The panel majority improperly draws adverse inferences against the party opposing summary judgment, inferring (1) that when the examiner requested "non-inventor" declarations, he expected experts who had no relationship with Ferring; (2) that Dr. Vilhardt understood that to be the examiner's request; and (3) that when Dr. Vilhardt contacted these distinguished scientists and obtained their affidavits -- an act my colleagues characterize as "completely natural" -- he and Ferring deliberately concealed their past connections, with the intent to deceive the PTO. The Supreme Court has reiterated that "Summary judgment in favor of the party with the burden of persuasion, however, is inappropriate when the evidence is susceptible of different interpretations or inferences by the trier of fact." Hunt v. Cromartie, 526 U.S. 541, 553 (1999).

The panel majority holds that "to create a genuine issue, the appellants bore the burden of submitting an affidavit from Vilhardt to contradict the movant's evidence of intent." Maj. op. at 19. Setting aside the fact that the movant did not put forward any evidence of intent, there is no requirement in law that the non-movant submit an affidavit in

opposing summary judgment. Ferring was free to rely on other more reliable forms of evidence, such as deposition testimony. See Fed. R. Civ. P. 56(c); 10A Charles A. Wright, Federal Practice and Procedure §2722 p.373 (3d ed. 1998) ("Because a deposition is taken under oath and the deponent's responses are relatively spontaneous, it is one of the best forms of evidence for supporting or opposing a summary-judgment motion.") In its response to the motion for summary judgment, Ferring stated that Dr. Vilhardt had never considered one way or another whether to include the omitted information, and pointed to Dr. Vilhardt's deposition testimony that he had "no idea" whether the patent office had asked for declarations from persons other than the inventors, and further that he had selected these scientists because they were "knowledgeable and connected to the field as to give a qualified opinion on the matter." See Anderson, 477 U.S. at 257 (to establish a genuine issue of material fact, the nonmoving party "need only present evidence from which a jury might return a verdict in [its] favor"). The panel majority's repeated assertions that Ferring "offered nothing" and that there was "no record evidence" to support its position are untenable, as are the credibility inferences it draws from Dr. Vilhardt's deposition testimony.<sup>4</sup> See Anderson v. Bessemer City, 470 U.S. 564, 575 (1985) (the task of

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4 My colleagues draw an adverse inference because Dr. Vilhardt initially did not recall the contacts, seventeen and thirteen years earlier, with the scientists concerning these affidavits. After being shown file correspondence indicating such contacts, Dr. Vilhardt explained that he had not recalled these contacts, had not understood what the questioner had meant by the term "affidavit" and that, while he didn't "remember distinctly what happened in those days," he believed that most of the correspondence was handled by the attorneys.

weighing the credibility of witnesses is for the trier of fact); Hunt, 526 U.S. at 552 (the district court erred in granting summary judgment, in that "it either credited appellees' asserted inferences over those advanced and supported by appellants or did not give appellants the inference they were due").

At a minimum, the issue should be remanded, on correct law. It is not the law that a declarant's past affiliations are always material, and it surely is not the law that "should have known" establishes deceptive intent, which requires scienter and deliberateness. On its face, "the involved conduct, viewed in light of all the evidence," does not "indicate sufficient culpability to require a finding of intent to deceive," the standard of Kingsdown, 863 F.2d at 876. It is improper to convict this inventor of fraudulent conduct based on inference, on summary judgment. That is not the law, and it is not a just procedure.