

**UNITED STATES COURT OF APPEALS**  
*for the*  
**FEDERAL CIRCUIT**

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THERASENSE, INC. (now known as Abbott Diabetes Care, Inc.)  
and ABBOT LABORATORIES  
*Plaintiff-Appellants,*

– v. –

BECTON, DICKINSON AND COMPANY,  
and NOVA BIOMEDICAL CORPORATION,  
*Defendants-Appellees,*

and

BAYER HEALTHCARE LLC,  
*Defendant-Appellee,*

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**On Appeal from the United States District Court  
For the Northern District of California  
Judge William H. Alsup**

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**BRIEF OF THE HOUSTON INTELLECTUAL PROPERTY  
LAW ASSOCIATION AS *AMICUS CURIAE*  
IN SUPPORT OF NO PARTY**

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**CERTIFICATE OF INTEREST**

Counsel for the Houston Intellectual Property Law Association certifies the following:

1. The full name of every party or amicus represented by me is:

Houston Intellectual Property Law Association

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

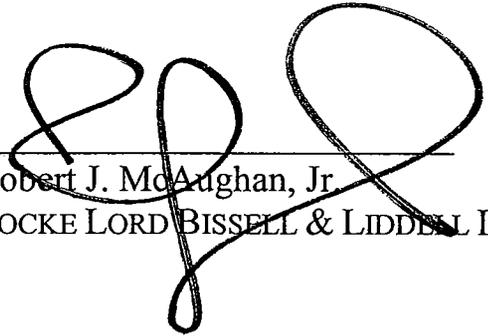
None

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

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Dated: August 2, 2010

  
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## **STATEMENT OF INTEREST**

*Amicus curiae* Houston Intellectual Property Law Association (“HIPLA”) is an association of over 400 lawyers and other professionals who work in the Houston, Texas area. Founded in 1961, HIPLA is one of the largest associations of intellectual property practitioners in the country. HIPLA’s mission is to promote the development and understanding of intellectual property law through regular meetings, sponsored CLE opportunities, and *amicus* briefs. As an organization, HIPLA has no stake in any of the parties to this litigation. No party to the appeal or its counsel has contributed monetarily or otherwise to this brief or its preparation. No HIPLA member has served as record counsel to any party in the subject of this appeal. HIPLA takes no position as to what result this Court should reach on appeal in its application of the law to the facts presented.<sup>1</sup>

All parties to this appeal have provided their consent to the filing of an *amicus curiae* in support of no party by HIPLA.

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<sup>1</sup> The positions and arguments set forth herein reflect the consensus view of the HIPLA *amicus curiae* committee and do not necessarily reflect the views of individual HIPLA members or the entities or law firms with which they are affiliated.

## ARGUMENT

### **I. A Modified “Materiality-Intent-Balancing Framework” for Inequitable Conduct Should Remain**

The defense of inequitable conduct is a significant defense in patent infringement cases. It also provides a genuine incentive for patent applicants, and those actively involved in the prosecution of patent applications, to comply with the duty of candor owed the United States Patent and Trademark Office (“PTO”) during the prosecution of patent applications through the submission of information to the PTO. And, it rectifies situations where a clear violation of this duty has occurred.

Necessarily, to serve these multiple purposes, a finding of inequitable conduct results in harsh and severe consequences, which serve as a disincentive to violate the duty of candor. A patentee may find an otherwise valid patent unenforceable and of no value. Individuals found to have participated in acts given rise to the defense may find their reputation and professional integrity destroyed.

Considering the significance of the defense and its highly destructive nature, HIPLA believes that maintaining a modified materiality-intent-balancing framework is the best approach both to preserve the continued viability of the defense (and the resulting incentive for disclosure of information to the PTO during prosecution of a patent application) and to protect patentees and individuals from unwarranted and unsupported claims of inequitable conduct. However, the

standards for determining materiality and intent where *actual fraud* is not established by clear and convincing evidence should be heightened as discussed below.

## **II. A Finding of Actual Fraud Should Be Sufficient—*But Not Essential*—for a Finding of Inequitable Conduct**

Consistent with this Court’s precedent, HIPLA believes that if a court finds: (i) that a person having a duty of candor and good faith to the PTO misrepresented or omitted material information; (ii) the misrepresentation or omission was made with a specific intent to deceive the PTO; and (iii) the PTO relied on the information or omission; (iv) to grant a patent claim, any resultant patent should be unenforceable due to inequitable conduct. *See, e.g., J.P. Stevens & Co., Inc. v. Lex Tex Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984) (“‘Common law fraud’ requires (1) misrepresentation of a material fact, (2) intent to deceive or a state of mind so reckless respecting consequences as to be the equivalent of intent (*scienter*), (3) justifiable reliance on the misrepresentation by the party deceived, inducing him to act thereon, and (4) injury to the party deceived, resulting from reliance on the misrepresentation.”) (citing *Norton v. Curtiss*, 433 F.2d 779, 793, (CCPA 1970).) In this, HIPLA is aligned the positions of other *amici curiae* that have suggested that a finding of actual fraud should render the resultant patent unenforceable.

However, in practice, the bar for a showing of actual fraud, and proof of a specific intent to deceive the PTO, is a high one indeed. Such a requirement would

significantly diminish the potential that a defendant could successfully advance an inequitable conduct defense and *importantly*, would reduce the incentive for those prosecuting patents before the PTO to submit information of known relevance to claims under examination. The diminishing of the likelihood of successfully advancing the defense of inequitable conduct if actual fraud is required is largely conceded by those *amici* advocating an actual fraud requirement. *See, e.g.*, Brief and Appendix of the American Bar Association as *Amicus Curiae* at 16, *Therasense, Inc. v. Becton, Dickinson & Co.*, No. 2008-1511 (Fed. Cir. Jun. 17, 2010) (“the ABA supports reforming the inequitable conduct doctrine by returning it to the common law fraud principles of specific intent and detrimental reliance embodied within the early Supreme Court precedent”) (“ABA *Amicus* Brief”). The resulting reduction in the likelihood of success of allegations of inequitable conduct would, unquestionably, weaken the defense.

Accordingly, while HIPLA believes that a showing of actual fraud should be sufficient for a finding of inequitable conduct, it *should not* be necessary. Rather, in instances where it can be shown, as a threshold matter, that: (i) a person with a duty of candor has withheld “material” information, using the heightened standard of materiality discussed below; and (ii) the single most reasonable inference from the evidence of record—*apart from the evidence of materiality*—establishes that the information was withheld with an intent to deceive the PTO into issuing the

patent or claim, the court should consider all the circumstances and balance the combined evidence of materiality and intent against the extreme penalty of rendering an entire patent unenforceable to determine whether a finding of inequitable conduct is warranted.

By establishing a heightened standard of materiality and requiring evidence of intent *apart from the evidence of materiality*, the framework set out above creates threshold barriers that will tend to reduce the number of unwarranted inequitable conduct allegations and provide a ready mechanism for dismissing those unwarranted allegations that are advanced. By allowing a balancing analysis if these heightened standards are met, the framework also provides a flexible approach that can be applied to a variety of situations and that maintains the practical viability of the defense as well as the resulting incentive for proper disclosure of information to the PTO during prosecution.

**III. The Standard for Materiality Should Be Higher than the Court’s “Reasonable Examiner” Standard, Yet Not as High as the “Rendered Invalid” Standard. The PTO Rules Should Play a Role in Defining Materiality in the Absence of Fraud.**

The dominant standard for materiality as applied by this Court has been the “reasonable examiner” standard, under which information is deemed “material” when “a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent.” *See, e.g., Symantec Corp. v. Computer Assocs. Int’l, Inc.*, 522 F.3d 1279, 1297 (Fed. Cir. 2008) (discussing the reasonable

examiner standard); *Digital Control Inc. v. Charles Machine Works*, 437 F.3d 1309, 1316 (Fed. Cir. 2006) (comparing reasonable examiner standard with new Rule 56). This standard is subject to much debate, is notoriously difficult to implement in practice, and provides little meaningful guidance to patent practitioners appearing before the PTO as to what must—and what need not—be disclosed during the prosecution of a patent application. This uncertainty has resulted in a tendency of many practitioners appearing before the PTO to err on the side of caution and cite significant numbers of references to the PTO, in some instances even overloading the patent examiners responsible for the examination of patent applications. *See, e.g.*, ABA *Amicus* Brief at 10 (arguing that current law “motivates patent attorneys and their clients to disclose every piece of prior art that may be remotely relevant to the subject matter being claimed”) (quoting *ABA Report with Recommendation* #107B at 2).

In apparent recognition of the inherently unclear nature of the “reasonable examiner” standard, the PTO modified its own rule in 1992 as to the types of information that it deems to be material. While also subject to debate, the PTO standards for materiality are more objectively-based than the “reasonable examiner” standard and define material information as follows:

[I]nformation is material to patentability when it is not cumulative to information already of record or being made of record in the application, and (1) establishes, by itself or in combination with other information, a *prima facie* case of unpatentability of a claim; or (2) it

refutes, or is inconsistent with, a position the applicant takes in: (i) opposing an argument of unpatentability relied on by the [PTO] or (ii) asserting an argument of patentability.

37 C.F.R. § 1.56(a)(2).<sup>2</sup>

While the PTO has gone farther in its rules in defining what is—and is not—“material” it has not gone as far as certain *amici* who seem to suggest that the standard for materiality should be such that the withheld information would have actually rendered at least one claim of the patent at issue invalid (“rendered invalid” standard). HIPLA’s concern with this “rendered invalid” standard is that the validity of the claim or claims at issue will most always, as a practical matter, be decided in the context of a patent infringement claim where the issue of validity is typically submitted to a jury. The jury, most certainly, would have been instructed that all patent claims have a presumption of validity and, therefore, must be proven invalid by clear and convincing evidence. Moreover, the analysis of materiality under these circumstances will be in conditions where the trial court may be bound by the jury’s “finding of validity” (more accurately that invalidity has not been established). *See Beacon Theatres v. Westover*, 359 U.S. 500, 508 (1959).

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<sup>2</sup> Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (Jan. 17, 1992) (explaining that Rule 56 was amended to “present a clearer and more objective definition of what the [PTO] considers material to patentability”).

Under these circumstances—with respect to the practical issue of patent enforceability—the inequitable conduct defense would nearly entirely collapse into the invalidity defense. Allegations of inequitable conduct would become no more than a mechanism for proving an “exceptional case” for an award attorneys fees, rather than an independent defense to an infringement claim. In addition, and even more importantly, the benefits to the public of a viable inequitable conduct defense—more complete disclosure to the PTO during prosecution and, presumably, an increase in the quality of issued patents—would not be met if the standard of materiality was commensurate with the standard required to prove invalidity.

For at least these reasons, a “rendered invalid” standard is improper. However, the Court’s current “reasonable examiner” standard is too broad and is unworkable. The appropriate middle ground approach would be to declare that, in the absence of actual fraud, information is “material” if it was material under the PTO rules applicable at the time of the examination of the patent at issue. This approach would be beneficial for several reasons:

First, it would, at least under the current PTO rules, provide a more objective standard for determining whether information is or is not material and indentifying the type of information required to be submitted to the PTO during prosecution of a patent application.

Second, it would provide a mechanism for the PTO to regulate disclosures so that it could implement rules to avoid the over-submission situation described in some of the other *amicus* briefs. *See, e.g.*, ABA *Amicus* Brief at 17 (arguing that allowing the PTO to determine what it considers material would “remov[e] the incentive to over-disclose information to the examiner”),

Third, it implements, in a more clear and objective manner, the likely intention of the “reasonable examiner” standard: that one should be motivated by fear of an ultimate finding of inequitable conduct to submit to the PTO that which a “reasonable PTO examiner,” under the applicable PTO rules as of the time of the examination, would expect to be submitted by an applicant.

This middle ground approach thus would provide an incentive for disclosure, would allow the PTO to implement rules to avoid over disclosure problems, and would ensure the viability of the inequitable conduct defense in patent litigation. Importantly, where a patent attorney prosecutes a patent under one understanding of materiality and discloses the references necessary under that standard (in her or her professional judgment), that attorney would not, years later, be judged under different, broader standard of materiality. To do so would certainly undermine the practice of patent law and would question a practitioner’s professional integrity on the basis of a standard about which the practitioner had no knowledge when making decisions regarding disclosure.

In connection with the issue of materiality, HIPLA believes that if the entirety of a prior art reference is before the PTO, attorney arguments constitute characterizations of that reference should not be deemed material. HIPLA is concerned that the Panel's opinion in this case affirming the lower court's finding of inequitable conduct undermines what was formerly a bright-line rule that attorney argument—characterizations of the prior art—are not material.

This Court has frequently noted what has been considered to be a bright line rule that attorney argument—characterizations of the prior art—are not material. *See, e.g., Innogenetics N.V. v. Abbott Labs.*, 512 F.3d 1363, 1378–79 (Fed. Cir. 2008) (“Innogenetics’ representation of the Cha PCT application amount to mere attorney argument and our precedent has made clear that an applicant is free to advocate its interpretation of its claims and the teachings of the prior art.”); *Life Techs., Inc. v. Contech Labs., Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000) (“[T]he inventors merely advocated a particular interpretation of the teachings of the Johnson article and the level of skill in the art, which the Examiner was free to accept or reject.”); *Young v. Lumenis*, 492 F.3d 1336, 1348 (Fed. Cir. 2007) (“We . . . fail to see how the statements . . . which consist of attorney argument and an interpretation of what the prior art discloses, constitute affirmative misrepresentations of material fact.”).

The justification for such a bright-line rule is clear—when a prior art reference is before an examiner, the examiner can reach his or her own conclusions about the prior art that is independent from the position argued by the prosecuting attorney. *See, e.g., Akzo N.V. v. United States Int’l Trade Comm’n*, 808 F.2d 1471, 1482 (Fed. Cir. 1986) (“The mere fact that Du Pont attempted to distinguish the Blades process from the prior art does not constitute a material omission or misrepresentation. The examiner was free to reach his own conclusion regarding the Blades process based on the art in front of him.”). To hold otherwise and permit mere advocacy regarding the disclosure of a prior art reference to constitute a material omission or misrepresentation would undermine the very role of a patent attorney at best, and at worst would conflict with the attorney’s ethical obligations to his or her client.

#### **IV. Intent Should be Separately Proven or Inferred, Without Consideration of Materiality.**

Intent should be separately proven by clear and convincing evidence, and should not be presumed from materiality. *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001). As this Court stated in *Molins PLC v. Textron, Inc.*:

[T]he 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 . . . mislead[ ] or deceiv[e] the PTO. 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.

48 F.3d 1172, 1181 (Fed Cir. 1995).

Some recent opinions from this Court seem to have moved far from this standard, and have applied a standard that where an applicant “knows or should have known” that information is material and makes a decision to withhold it from the PTO, intent to deceive is inferred. *See, e.g., Cargill, Inc. v. Canbra Foods, Ltd.*, 476 F.3d 1359, 1368 (Fed. Cir. 2007) (“When an applicant known or obviously should know that information would be material to the examiner . . . but the applicant decides to withhold that information, ‘good faith’ does not negate an intent to manipulate the evidence.”). This standard not only conflicts with *Kingsdown Med. Consultants, Ltd. v. Hollister, Inc.*, 863 F.2d 867 (Fed. Cir. 1988) (*en banc*), but also invites the application of “20/20 hindsight” and is far too subjective to be equitably applied to an inequitable conduct inquiry.

To clarify this issue, HIPLA urges that this Court embrace the view of the panel in *Star Scientific*, that while intent may be inferred from indirect or circumstantial evidence, “such evidence must still be clear and convincing, and evidence drawn from lesser evidence cannot satisfy the deceptive intent requirement.” *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F. 3d 1357, 1366 (Fed. Cir. 2008). Furthermore, the inference of intent should only be made where it is “the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.” *Id.*

As this Court has frequently stated, in the context of inequitable conduct, that intent can rarely be proven directly, and such intent can be inferred from circumstantial and indirect evidence. *See, e.g., Cargill*, 476 F.3d at 1364 (“Intent rarely can be, and need not be, proven by direct evidence. . . . Instead, an intent to deceive is usually inferred from the facts and circumstances surrounding the conduct at issue.”); *Critikon, Inc. v. Becton Dickinson Vascular Access, Inc.*, 120 F.3d 1253, 1256 (Fed. Cir. 1997) (“Direct evidence of intent or proof of deliberate scheming is rarely available in instances of inequitable conduct”). *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1191 (Fed. Cir. 2006) (“[I]ntent need not, and rarely can, be proven by direct evidence”) (quoting *Merck & Co., Inc. v. Danbury Pharmacal, Inc.*, 873 F.2d 1418, 1422 (Fed. Cir. 1989)). However, the standard should be applied consistently that when circumstantial or indirect evidence is used to infer intent, that evidence must still be clear and convincing. *Star Sci.*, 537 F.3d at 1366 (citing *Ferring*, 437 F.3d at 1186). Moreover, “the inference must not only be reasonable in light of that evidence, but it must also be the ***single most reasonable inference*** able to be drawn from the evidence to meet the clear and convincing standard.” *Star Sci.*, 537 F.3d at 1366–67 (citing *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008)) (emphasis added).

HIPLA believes that while intent should be inferred from indirect and circumstantial evidence, a finding of materiality, even a high degree of materiality, should never be *sufficient* to meet the intent requirement.

The requirement of proof of intent wholly separately from considerations of materiality has been exemplified in a number of this Court's decisions. *See, e.g., Optium Corp. v. Emcore Corp.*, 603 F.3d 1313, 1321 (Fed. Cir. 2010) (holding that evidence of materiality alone could not support a finding of intent); *Astrazeneca Pharms. LP v. Teva Pharms. USA, Inc.*, 583 F.3d 766, 770 (Fed. Cir. 2009) (“Intent to deceive cannot be inferred from a high degree of materiality alone, but must be separately proved to establish unenforceability due to inequitable conduct.”) ; *Abbott Labs. V. Sandoz, Inc.*, 544 F.3d 1341, 1357 (Fed. Cir. 2008) (“Materiality, even if found, does not establish intent.”) (quoting *Allied Colloids, Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed. Cir. 1995)). In these cases, this Court first addressed intent and, finding no intent to deceive, reversed the lower court's finding of inequitable conduct, without addressing materiality of the information withheld from the PTO. There, failure to meet the clear and convincing proof of intent ended the inquiry, as no degree of materiality—no matter how high—could overcome the lack of intent.

While intent to deceive may be inferred from circumstantial and indirect evidence, intent to deceive should not be based on the “known or should have

known” standard. This standard was properly rejected in *Kingsdown*. See *Kingsdown*, 863 F.2d at 876 (“We adopt the view that a finding that particular conduct amounts to ‘gross negligence’ does not of itself justify an inference of intent to deceive; the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive.”). Rather, intent to deceive should only be inferred from circumstantial or indirect evidence where there is clear and convincing evidence that “the applicant made a deliberate decision to withhold a known material reference” from the PTO. *Baxter Int’l, Inc. v. McGaw, Inc.*, 149 F.3d 1321, 1329 (Fed. Cir. 1998) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

Cases involving the submission of misleading information to the PTO, rather than omission of information, should be governed by a similar heightened standard involving the showing of a deliberate decision to provide known material information to the patent office.

Considering that the recent cases that have applied the “known or should have known” standard to find an intent to deceive, like *Cargill*, all derive support eventually from the portion of *Driscoll v. Cebalo*, 731 F.2d 878, 885 (Fed. Cir. 1984) that was overruled by *Kingsdown*, the position regarding the standard for intent that HIPLA advocates is merely clarification that the *Kingsdown* standard is

the law. It can be seen from the rise in the assertion of the inequitable conduct defense, as well as numerous outcomes yielding unenforceable patents, that the standard is being misinterpreted and misapplied by the district courts as well as panels of this Court. *See, e.g., Aventis Pharma S.A. v. Amphastar Pharms, Inc.*, 525 F.3d 1334, 1350 (Fed. Cir. 2008) (Rader, J., dissenting) (“Merging intent and materiality at levels far below the *Kingsdown* rule has revived the inequitable conduct tactic.”).

HIPLA believes that the recent cases clearly demonstrate that the gross negligence, “known or should have known” standard is far too low. However, if the applicant actually knew that the information was material and intentionally withheld that information, and had *no* good faith reason such as a belief the information was cumulative, then the Courts should infer an intent to deceive. If the evidence shows that the applicant, at the time of prosecution, had good faith basis for withholding the information, then the intent to deceive would not be the single most reasonable inference and there should be no inference of an intent to deceive.

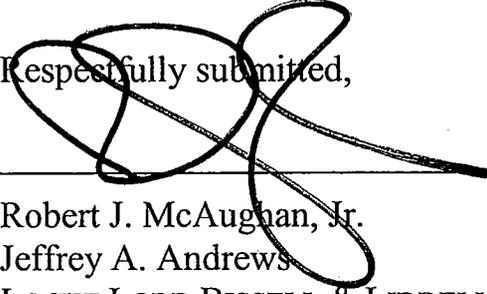
### **CONCLUSION**

The defense of inequitable conduct is an important defense for accused patent infringers and is necessary to provide an incentive to parties pursuing claims before the PTO to comply with their duty of candor under Rule 56. These two

justifications for the doctrine must be balanced so that the defense of inequitable conduct is not out of reach of accused infringers—as this would indeed be inequitable—but yet not applied too easily—as this would unfairly exact a high price on both patentees and patent practitioners. With these considerations in mind, HIPLA believes that the overall materiality-intent-balancing framework should not be replaced. However, it should be modified and clarified such that the standard for materiality is in agreement with the standard applied by the PTO, and the standard of intent follows that established in *Kingsdown* and applied in, e.g., *Star Scientific*. The standard for intent should not be “actual fraud,” as this would, in practice, eliminate inequitable conduct as a viable defense to patent infringement.

Date: August 2, 2010

Respectfully submitted,

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## Certificate of Service

I hereby certify that 2 (2) copies of the foregoing BRIEF OF THE HOUSTON INTELLECTUAL PROPERTY LAW ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF NO PARTY were served on the 2nd day of August, 2010, by Federal Express, to those addressed below:

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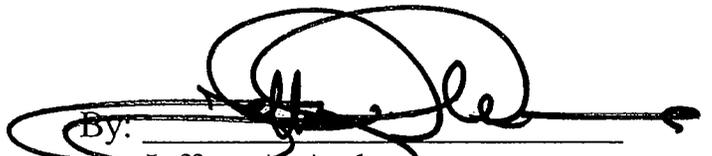
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