2008-1248

United States Court of Appeals
FOR THE FEDERAL CIRCUIT

**ARIAD PHARMACEUTICALS, INC.,
MASSACHUSETTS INSTITUTE OF TECHNOLOGY,
THE WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, AND
THE PRESIDENT AND FELLOWS OF HARVARD COLLEGE,**

Plaintiffs-Appellees,

v.

ELI LILLY & COMPANY,

Defendant-Appellant.

Appeal from the United States District Court for the District of Massachusetts in Case No. 02-CV-11280, Judge Rye W. Zobel

BRIEF OF AMICUS CURIAE MEDTRONIC INC. IN SUPPORT OF ELI LILLY & COMPANY

William P. Atkins
Jack S. Barufka
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Boulevard
McLean, Virginia 22102
(703) 770-7900

November 16, 2009

CERTIFICATE OF INTEREST

Counsel of record for *amicus curiae* Medtronic, Inc. certifies the following:

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

Medtronic, Inc.

2. The party represented by me as *amicus curiae* is the real party in interest.

3. The parent companies, subsidiaries (except wholly owned subsidiaries), and affiliates that have issued shares to the public, of the party or *amicus* represented by me are: Medtronic, Inc.

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

William P. Atkins
Jack S. Barufka
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Boulevard
McLean, Virginia 11201
(703) 770-7900

Dated: November 16, 2009

Wm. P. Atkins
WILLIAM P. ATKINS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

Other Authorities

STATEMENT OF INTEREST OF AMICUS CURIAE

Medtronic, Inc. ("Medtronic") is a world leader in medical device technology and a company committed to innovation. The company's first life-changing device – a battery-powered, wearable cardiac pacemaker – was the foundation for many more Medtronic devices that use its proprietary technologies to improve the lives of millions of people. Medtronic continues to innovate and contribute to human welfare through the creation and application of biomedical technology by researching, designing, manufacturing, and selling devices that alleviate pain, restore health, and extend human life. Medtronic's innovations include technologies beyond those of its original mechanical and electrical roots. Today these innovations include combination medical devices involving the chemical and biological arts. Accordingly, Medtronic's interest is not that of another large company taking defendant-appellant's position, but rather one of a company that is committed to innovation in a quickly evolving marketplace where predictable and unpredictable technologies are converging.

Medtronic has also been involved in numerous patent cases, as both plaintiff and defendant. Thus, Medtronic's considered interest is of one who has sat at both tables in courtrooms, here in the United States and abroad, who has pursued patent protection and invalidity with equal vigor. With this culture of technical

innovation and business experience, Medtronic has acquired a unique and pragmatic legal perspective.

This amicus believes that elimination of the written description requirement would do profound harm to innovation and the global competitive landscape of the medical device industries, as well as others. This amicus' interest is to advance a reliable and unambiguous legal standard which promotes and rewards entrepreneurship, as well as fair competition. Medtronic takes this position, not as an academic or intellectual exercise, but because of its unique position as a large company straddling all areas of technology, who deals with real-world issues of intellectual property valuation on a daily basis.

The source of authority to file this amicus curiae brief is found in the Order of this Court dated August 21, 2009.

SUMMARY OF THE ARGUMENT

The United States patent system is out of balance and, as a result, small and large companies find it increasingly difficult to operate effectively in the marketplace given the uncertainty. This uncertainty is due in large part to a patent owner's ability to claim and assert inventions that were never contemplated by the original inventor. Eliminating the written description requirement would compound this problem as no other statutory or legal rule provides adequate protection against this practice.

Inventors control what they claim when they file their patent applications. Therefore, amicus' position is that an applicant should enjoy patent protection that is no broader than the inventions claimed in the originally filed claims that they themselves chose to file. The obligation to provide notice to the public of the invention (i.e., the scope of protection to which the applicant believes they are entitled) should be upon the applicant. It should not be cloaked in uncertainty, as it currently is, until the patent is deciphered by a court and jury years after its filing.

Current law enables applicants to claim subject matter during prosecution for which there is no literal "written description," but instead may be found by only combining disparate parts of the specification. In addition, the current written description requirement allows applicants to broadly rename elements during prosecution so as to give them a breadth not contemplated at filing. This puts the

public at the peril of late-claiming applicants who did not fairly disclose what they believed they invented at the time their application was filed. This deficiency in the law permits patent owners to rely on a subjective, uncertain boundary defining the scope of their inventions, which forces the public to guess the potential scope of intellectual property rights when analyzing patents to decide whether or not to bring new, potentially life-saving products to the market.

At least three reasons exist why a written description requirement is needed in addition to enablement. First, without a written description clause, the "enabled" inventions enjoy an indefinite, subjective boundary due to an additional layer defined by "without undue experimentation." Second, without written description, publication under 35 U.S.C. § 122(b) becomes meaningless. Third, the predicate basis for a § 112, ¶ 2 analysis disappears.

This amicus brief ends with a short discussion on the real world impact that innovation will suffer if the written description requirement is abandoned by this Court.

This amicus agrees with the answers given in the brief of defendant-appellant Eli Lilly & Co. ("Lilly Br.") to this Court's en banc questions. A written description requirement is necessary and it should be strengthened by requiring patentees to clearly define their invention at the time they file their application. To

ensure proper notice, the scope of later filed or amended claims should be limited to those inventions applicants chose to claim in their originally filed claims.

ARGUMENT

I. THE WRITTEN DESCRIPTION REQUIREMENT SHOULD NOT JUST BE MAINTAINED, IT SHOULD BE STRENGTHENED

A. The Public Notice Function Of Patents Is Critical To Competition And The Current Written Description Requirement Is Poor At Giving The Public Notice

Our patent system is designed to encourage and reward innovation by granting patents that give the public notice of the inventions. The ability of applicants to broaden and/or twist claims during prosecution makes it extremely difficult for the public to determine the scope of claims in pending patent applications, as well as the scope of claims in granted patents. This harms competition and innovation, seriously inhibits the ability of companies to evaluate the value and breadth of its own and its competitor's intellectual property, and reduces the predictability of success in litigation. When the public cannot determine what possible configuration a pending patent claim may take because a specification provides a veritable matrix of possibilities, the public notice function is also undermined. Predicting the potential scope of yet-to-issue patent claims or the likelihood of success of a § 112, ¶ 1 defense is a guessing game, at best. Early, definitive, and ongoing notice of what the inventors can most broadly claim as their inventions (i.e., what they invented) would fix this problem. Setting the

originally filed claims as the boundaries of the conceived inventions gives the public true notice.

Medtronic recognizes that the proposed written description requirement would be a significant change in existing patent practice, one that would likely require significant increases in up front prosecution costs. However, having a deep commitment to innovation, involving the creation and sustenance of a robust patent portfolio, Medtronic advocates for this change in order to better serve the public who rely on companies like Medtronic to bring life-saving products to market.

B. The Originally Filed Claims Provide The Clearest Written Description Of What the Inventor Regards As His Invention

The position of this amicus is that the claims, as originally filed, provide the clearest written description of an inventor's invention. Therefore, the allowable scope of any later claims should not be broader than those claims that the inventor chose to put in his or her patent application in the first place.[1] With the scope limited to that which is contained within the originally filed claims, claim language in subsequently amended claims should be limited to language that finds direct and unambiguous support in the specification. Applicants and their counsel should not be allowed to pick and choose words from disparate parts of the specification or

---

[1] It is recognized that this could be a challenge for *pro se* inventors due to a lack of involvement of patent attorneys or agents. Therefore, some flexibility should be considered for their applications.

use broad variations of specific words they chose to include in the specification, when amending their claims during prosecution. The remainder of the specification can be used to ensure that these claimed inventions are actually enabled.

C. Applicants Should Be Permitted To Claim Only Subject Matter That Was Actually "Described In Writing" And Not That Which Might Be "Derived From The Writing"

The case law currently allows applicants to claim subject matter for which there is no actual "written description" in the specification, but which may be "inherent" in the specification. *Kennecott Corp. v. Kyocera Int'l, Inc.*, 835 F.2d 1419, 1423 (Fed. Cir. 1987). The law permits inventors to later claim subject matter which may be derived from a specification that did not fairly disclose such subject matter. In these situations, the specification does not teach or notify the public (e.g., upon publication) of a potentially much broader or different claim scope than what has been literally "described." At the very least, the purpose of the "written description" requirement should be to require such fair written notice. Without such notice, the public cannot rely on the published claims or a specification in developing its own technology or analyzing a competitor's patent, but is instead at the mercy of overreaching applicants and their counsel who take advantage of the currently permissive application process.

Inventors should have the burden of actually providing a "written description" of what they believe they invented at the time they filed their patent application. Inventors should not be permitted to modify their claims in a manner that was not directly and unambiguously described when the application was first filed. Inventors are best suited to put the public on notice of what they invented, and their own patent claims, as first filed, are the best place for such notice. Such a requirement would provide greater clarity and predictably to the public. That, in turn, would improve the investment decisions of businesses and promote better competition, improve the library of prior art, and force a clearer and more predictable claim construction, thereby reducing litigations and its related costs as well as its unpredictability.

D. The Inventor's Declaration And The Prior Art Should Prevent The Problem Of Overly-Broad Claims Being Filed With The Application

One might argue that a rule requiring applicants to be limited to a claim scope that cannot exceed the scope of the claims as filed would promote filing of unreasonably broad claims in an application. However, when claims are filed, they are accompanied by an inventor's declaration or oath, which requires that "[t]he applicant shall make oath that he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter, or improvement thereof, for which he solicits a patent . . ." 35 U.S.C. § 115. In

addition, the oath or declaration must "[s]tate that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought." 37 C.F.R. ¶ 1.63(4). Thus, an inventor is prohibited from filing claims that are broader than what the inventor believes to be patentable over the prior art. If an inventor attempts to do so, he or she would be subject to the penalties associated with the filing of a false oath or declaration: fine or imprisonment or both; not to mention unenforceability of the entire granted patent.

In addition, inventions that are subject to such overclaiming will have to confront potentially serious issues. First, the consequence of having claims that read on the prior art is severe. Second, applicants amending their claims will be entangled in prosecution history estoppel, further limiting their claims. Third, efforts to later amend the claims in light of the prior art may find that the available claim scope is not available because there is no written support for the invention.

II. THREE REASONS WHY ENABLEMENT ALONE DOES NOT PROVIDE A WRITTEN DESCRIPTION

With the written description requirement in place: (1) an applicant is held to what they chose to describe in their application on image compression software;[2]

---

[2] *LizardTech , Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1346 (Fed. Cir. 2005)(the written description requirement prevented the patentee from claiming subject matter that the inventor did not contemplate at the time the application

(2) applicants are prevented from late claiming that which they did not describe in their mechanical application or even invent;[3] and (3) an applicant for a chemical patent cannot claim a genus, if they did not clearly invent it.[4] All three of these decisions are based on a written description requirement, not enablement. This Court is considering abandoning this safeguard, however, in the hopes that enablement alone will be sufficient. Enablement alone cannot provide the clarity and predictability needed for a properly functioning patent system.

A. Enablement Standard Of "Without Undue Experimentation" Is An Unwritten And Indefinite Void Available For Later Manipulation

To meet the enablement requirement, a patent applicant must enable one of ordinary skill in the art to be able to make and use the claimed invention "without undue experimentation." *In re Wands*, 858 F.2d 731, 736 (Fed. Cir. 1988). "The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of

---

was filed, but only later attempted to claim after learning of competing technologies).

[3] *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1474 (Fed. Cir. 1998)(predicable arts - a single location for "controls" taught in the specification, but then claimed merely on the sofa and this Court properly found a lack of written description, even though this decision was limited by later caselaw).

[4] *In re Ahlbrecht*, 435 F.2d 908, 911-12 (CCPA 1971)(unpredictable arts - the Court agreed that it is wrong to allow an applicant to claim that which he or she did not clearly invent, even if a genus is enabled). Consider the reverse scenario as well, where an inventor enables a genus, but does not enable the claimed species. *See* cases cited at Lilly Br. at p. 36.

the invention and the state of the art." *Id.* at 737. Because this "standard of reasonableness" varies with the nature and state of the art, "without undue experimentation" creates an indefinite void between what is enabled and what is claimed; a void that can be manipulated. If a claim recites a limitation that is not supported by the specification, the patentee can argue that the claim is nonetheless enabled because one of ordinary skill in the art would understand that the invention as claimed would work "without undue experimentation," in light of the specification.

If the written description requirement is abandoned, applicants will only need to find support for their eventual patent claims through an enablement clause that encompasses an indefinite, unwritten boundary of "undue experimentation." A written description requires a description that is actually a description, and in writing, not merely an enablement that allows unwritten, indefinite experimentation.

B. Eliminating Written Description Contradicts The Public Notice Function Of 35 U.S.C. § 122

Under 35 U.S.C. § 122(b), patent applications are now published eighteen months from "the earliest filing date for which a benefit is sought." This was passed to harmonize the United States laws with international law and to "ensure that American inventors will be able to see the technology that our foreign

competition is seeking to patent much earlier than is possible today."[5] The legislative history is clear: "[t]he burden should be on the applicant to initially draft a schedule of claims that gives adequate notice to the public of what she is seeking to patent." *Id.* at S14719 (col. 3, lines 32-36). This legislative history supports the view that the originally filed claims are the best way to provide the public with notice and that the burden is on the applicant to do so.

Eliminating the written description requirement is contrary to the objective of publishing applications to provide the public with notice and because inventions that only enable can be subjectively broadened by "undue experimentation." This allows a potential claim scope that is well beyond that which is clearly enabled and well beyond that which a person of ordinary skill in the art would understand the inventor to have possessed or taught at the time of filing.

C. §112, ¶ 2 Needs A Basis For What "Applicant Regards As His Invention"

The written description requirement in ¶ 1 provides a predicate basis for 35 U.S.C. § 112, ¶ 2 which states: "The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention."[6] (Emphasis added). The PTO, the public,

---

[5] Congressional Record, November 17, 1999, page S14708, S.1948, statements of Senator Lott (col.3, Subtitle E, lines 19-23).

[6] *See* MPEP § 2171("The inquiry during examination is patentability of the invention as applicant regards it. If the claims do not particularly point out and

and even the Courts need to know what "the applicant regards as his invention" in order to apply § 112, ¶ 2. Without a concrete, defined, meaningful written description requirement, it is impossible to determine what the applicant "regards as his invention" if the only means of figuring that out is an enabled embodiment wrapped in an indeterminate "undue experimentation" standard. A written description requirement is needed, and it should be the claims as originally drafted.

III. THE IMPACT OF A LACK OF WRITTEN DESCRIPTION ON INNOVATION IN MEDICAL TECHNOLOGY

The simultaneous use of multiple technologies is playing a significant role in the development and design of products in the medical device industry. This is because the convergence of a wide range of technologies is needed to provide solutions to a number of disease states which medical devices alone cannot address. Therefore, the growth and future of the medical device market will depend on innovation which integrates mechanical technology with biologics, pharmaceuticals, nanotechnology and communication systems, among others. With this integration and the convergence of many scientific and technology breakthroughs, innovation in medical technology is accelerating.

---

distinctly claim that which applicants regard as their invention, the appropriate action by the examiner is to reject the claims under 35 U.S.C. § 112, ¶ 2. *In re Zletz*, 893 F.2d 319, 13 USPQ2d 1320 (Fed. Cir. 1989). If a rejection is based on 35 U.S.C. § 112, ¶ 2, the examiner should further explain whether the rejection is based on indefiniteness or on the failure to claim what applicants regard as their invention. *Ex parte Ionescu*, 222 USPQ 537, 539 (Bd. App. 1984)").

In this fast-paced environment, medical device companies use a broad range of intellectual property law strategies to protect their intellectual assets. Patents play an important role in protecting these innovations. In fact, medical device companies such as Medtronic depend heavily on patents to protect their intellectual property rights and to exploit their innovations. Patents are also one of the most important tools that are used to evaluate the merits of a particular technology development or investment. Since investors, research and development organizations, and businesses rely on patents as a gauge to determine the extent of third party intellectual property boundaries, broad claims based on shallow descriptions would stifle innovation, discourage investments and severely limit commercialization. Given the convergence of technologies in the medical device industry and the attendant, vast investment in innovation, overturning *Ariad* would have an enduring negative impact on this industry.

In an attempt to provide the Court with real examples of advances in hybrid technologies which may be affected by reversing the *Ariad* decision, this amicus respectfully submits a series of examples drawn from its broad experience as a global leader in medical technology innovation. The examples underline the grave potential consequences of abandoning the written description requirement in part because these new medical device products combine technologies such as mechanical, electrical, electrochemical, software, and the like (i.e., the predictable

arts) with biotechnology, gene therapy, pharmaceuticals, chemical, and the like (i.e., the unpredictable arts). These unpredictable arts involve complex chemical and biological reactions which make it difficult to pinpoint the exact boundaries and distinguishing features of each invention.

Essential to the written description requirement is the disclosure associated with the embodiments of the invention. In the predictable arts, such as software for example, describing the executional or functional aspects of an embodiment would require sufficient description of the invention to prevent patentees from claiming an unbounded scope of protection. In sharp contrast, an *Ariad* reversal, applied to the unpredictable arts, would allow a claim encompassing several types of drugs without specific and clear disclosure of the elements of the claimed subject matter.

In this regard, a hybrid invention which integrates both predictable and unpredictable arts will face two inconsistent standards if *Ariad* is reversed because the amount of guidance or direction which is normally available from the disclosure in an application will not be present in the unpredictable arts. In the emerging biotechnology arts for example, where little is available in the prior art, the specification needs to contain more details to teach how the invention can be made or used. While the elimination of the written description or its dilution thereof may simplify the prosecution of patents it would make validity analysis

almost impossible and unreliable. It would also impact obviousness and anticipation analyses thus yielding more ambiguity and uncertainty in the law and the resultant patents. Therefore, the potential impact of eliminating the written description on medical technology innovation would be immediate, swift, and severe because it would undermine and discourage research and development in hybrid technologies.

For example, a control system for the delivery and management of drugs with remote patient monitoring may integrate pharmaceuticals, medical devices, software, and communication systems. The typical claim language which covers such a system would claim the software, the device, the communication system, and the drug. This poses a dilemma to the public if the written description is no longer required because undue and endless experimentation may be required to understand and gain legal notice and knowledge as to what is the distinguishing feature(s) of the claimed invention. More specifically, as more and more medical device inventions contain various elements from multiple technologies, composed of both the predictable and unpredictable arts, the possible combinations which yield the invention may be numerous. Without a written description, it would be impossible to know and understand what the invention covers and where its boundaries lie in view of the prior art.

Another illustrative example is where a drug-device interaction system monitors and manages device and drug therapies to optimize patient benefits from each therapy. Specifically, device therapy which may likely be triggered because of physiological effects of a drug or drugs is managed by monitoring the duration of actual drug delivery time and lingering influence of the drug. This will enable the device to either deploy or withhold device-induced therapy simultaneous with the drug therapy or after a predetermined time interval. A patentee claiming such a system would be required to recite elements from the device, communication and drug(s) implemented thereof. Here again, the lack of a written description would try to fuse together claim elements which originate from two differently positioned arts if the written description requirement is eliminated. Specifically, in the example, the applicant can define the elements of his claim(s) which relate to the predictable art with more certainty (in view of the prior art which provides the earlier existing invention in sufficient detail and also upon reliance of the predictability of the art); whereas identification of the inventive elements from the unpredictable art portion of the invention would be impossible. This is because, the availability of little or no prior art would make it difficult to distinguish the invention. Further, if the written description is voided future inventions would be highly ambiguous because subsequent inventors would need to guess as to what are the teachings and boundaries of prior patents.

Yet another illustration relates to nanotechnology techniques such as lab on a chip or micro fluids. A lab on a chip is generally made up of micro or nanofabricated channels through which cellular/biologic fluid and chemicals flow. These tiny chips can be designed to perform various diagnostic, monitoring and treatment systems in combination with medical devices. In this case, a patentee claiming such a system would likely draft a claim with elements combining the unpredictable and predictable arts.

A further example includes nano or molecular imaging (nanotechnology probes) which makes in vivo molecular activity and action visible, quantifiable and traceable. In the future, nanotechnology probes will be tuned to specific cellular signals to enable physicians to find disease conditions much earlier. Such systems could be integrated with medical devices to manage and administer various therapies. Similar to the examples above, a patentee claiming molecular imaging integrated with drugs or biologic agents and a medical device would need to compose elements selected from both the predictable and unpredictable arts.

The future of predictive and preventative medicine including therapy delivery and disease management will be highly leveraged by the interface between biologics, nanotechnology, communication systems and medical devices. This interface will not only change health care but also the process of scientific research, product development, and the competitive and innovation environment.

Thus, the impact of this Court's decision will become prevalent in the future as medical device companies develop more complex systems which include a combination of technologies spanning across the predicable and unpredictable arts.

Medical technology innovations promise a great future in heath care and are poised to deliver on that promise. To promote these valuable innovations the statutory standards of patentability, including the requirement for a written description which facilitates full and complete disclosure of inventions, need to be stable and reliable. In this regard, abandonment of the written description requirement would create ambiguity and unpredictability, stands against long established standards of patent law, and is poised to create questionable patents which harm innovation, discourage investment, stifle competition and would likely result in massive patent litigation thus impacting the bright economic future of the medical device industry.

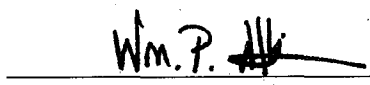
CONCLUSION

The public, including companies in predictable and unpredictable arts, should be able to reasonably understand what an inventor invented and what he or she might reasonably be able to claim. This is why the patent laws are made up of several delicately balanced, interworking requirements, each serving a vital role. No one part of the patent statute can adequately compensate for the other parts and this is why the written description requirement needs to be reinforced. This is why

this amicus submits that the initially filed claims, which are part of the specification, represent the clearest delineation of what the applicant regards as his invention. If left with only the enablement requirement, the public will be at greater risk of inventors and their counsel contorting claims to cover that which they did not invent. Thus, a written description requirement separate from the enablement requirement should not be abandoned, and instead it should be maintained and strengthened to improve the certainty of our patent system that drives innovation and is vital to our economy.

Respectfully submitted,

PILLSBURY WINTHROP SHAW PITTMAN LLP

BY: 

WILLIAM P. ATKINS

DATED: November 16, 2009

CERTIFICATE OF SERVICE

Ariad Pharmaceutical v. Eli Lilly, 2008-1248

I, William P. Atkins, being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Pillsbury Winthrop Shaw Pittman LLP was retained by Medtronic, Inc., Attorneys for Amicus Curiae, to print this document. I am an attorney at Pillsbury Winthrop Shaw Pittman, LLP.

On the 16th day of November 2009, I caused 2 copies of the within **Brief of *Amicus Curiae* Medtronic, Inc.** to be served upon the following:

James W. Dabney
Fried Frank Harris
Shriver & Jacobson LLP
One New York Plaza
New York, New York 10004
(212) 859-8000

Charles E. Lipsey
Finnegan, Henderson, Farabow
2 Freedom Square
1195 Freedom Drive
Reston, Virginia 20190
(571) 203-2399

Attorney for Defendant-Appellant

John M. Whealan
12 Sunnyside Road
Silver Spring, Maryland 20910
(202) 994-2195

Kenneth J. Burchfiel
Sughrue Mion, PLLC
2100 Pennsylvania Avenue, N.W.
Suite 800
Washington, D.C. 20037
(202) 293-7060

Attorney for Amicus Novozymes

Leora Ben-Ami
Kaye Scholer, LLP
425 Park Avenue
New York, New York 10022
(212) 836-7203

Attorneys for Plaintiffs-Appellees

via first class mail and email.

Unless otherwise noted, 30 copies have been hand-delivered to the Court on the same date as above.

Wm. P. Atkins

CERTIFICATE OF COMPLIANCE

I do hereby certify that this Amicus Curiae Brief was prepared using Microsoft Word and that the Brief is in compliance with the type-volume limitations contained in Fed. R. App. Proc. 32(a)(7)(B). The Brief is prepared in 14-point Times New Roman type and contains 4461 words.

Dated: November 16, 2009.

Wm. P. Atk

William P. Atkins
Pillsbury Winthrop Shaw Pittman LLP
1650 Tysons Boulevard
McLean, Virginia 22102
Tel: (703) 770-7900
Fax: (703) 770-7901