From:
Sent: Monday, March 08, 2010 5:12 PM
To: patent_quality_comments
Subject: Attached Comments from PhRMA

Attached are comments in response to the "Request for Comments on Enhancement in the Quality of Patents." Please do not hesitate to contact me if you have any questions.

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David E. Korn
Senior Assistant General Counsel

PhRMA

March 8, 2010

VIA EMAIL: patent_quality_comments@uspto.gov

Mail Stop Comments – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attention: Kenneth M. Schor, Senior Legal Advisor
Pinchus M. Laufer, Legal Advisor

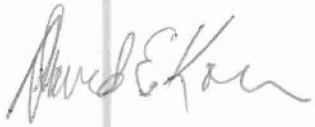
Dear Mr. Laufer and Mr. Schor,

I am writing on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") to convey the views of PhRMA's members in response to the "Request for Comments on Enhancement in the Quality of Patents," 74 Fed. Reg. 65093 [Docket Nos.: PTO-P-2009-0054 and PTO-P-2010-0004]. PhRMA's members are leading pharmaceutical research and biotechnology companies devoted to researching and developing new medicines to allow patients to live longer, healthier and more productive lives. PhRMA members lead the way in finding cures and new treatments as well as in developing critically important improvements in existing therapies. Strong patent protection is required in order to promote the innovative research necessary for such advances and to make available to society the benefits of that research.

The enclosed comments include views of PhRMA's members on ways to achieve the laudable goal of enhancing patent quality. PhRMA's members support this goal, and would welcome further dialogue with the PTO on ways to achieve it.

Please feel free to contact me with any questions or concerns you may have.

Sincerely,



David E. Korn
Senior Assistant General Counsel

Enclosure

Comments of the Pharmaceutical Research and Manufacturers of America in Response to the PTO's Request for Comments on Enhancement in the Quality of Patents

The Pharmaceutical Research and Manufacturers of America ("PhRMA") appreciates the opportunity to submit comments in connection with the Patent and Trademark Office ("PTO") Request for Comments on Enhancement in the Quality of Patents.[1/] Given the number of controversial rule packages proposed by the PTO over the past few years, the PTO should continue to improve the transparency, notice, and comment processes in cases of significant proposed rulemaking. If the PTO and user community understood each other earlier in the process, there could be more streamlined and efficient ways to find common ground and achieve common goals.

PhRMA's member companies are leading research-based pharmaceutical innovators devoted to developing medicines that allow patients to live longer, healthier, and more productive lives. PhRMA's membership ranges in size from small start-up research firms to multi-national, multi-billion dollar corporations that employ tens of thousands of Americans, and encompass both research-based pharmaceutical and biotechnology companies.

PhRMA members have a strong interest in efforts designed to improve the patent prosecution process and enhance the quality of patents. In this submission, we will describe the role that patents play in the work of PhRMA's member companies, and respond to the PTO's request for input on ways to enhance and measure patent quality.

I. Patent Rights Are Essential To Pharmaceutical Innovation

The research-based pharmaceutical sector is one of the most knowledge-intensive enterprises in the U.S. economy, and is responsible for 80% of the world's global healthcare biotechnology research and development ("R&D").[2/] In 2008, the pharmaceutical sector invested $65.2 billion in R&D. The vast majority of this R&D investment – $50.3 billion – was invested by PhRMA's member companies, an increase of over $2 billion from 2007. Of that amount, roughly 70%, or $38 billion, was invested in the U.S. This sector also is the source of high-quality, high-value jobs and economic growth. Analyses show that the industry supported more than 3.2 million jobs, and directly employed more than 686,000 Americans in 2006.[3/] The industry's direct contribution to GDP in 2006 was $88.5 billion – more than triple the average contribution of other sectors.[4/]

1/ 74 Fed. Reg. 65093-100 (Dec. 9, 2009).

2/ Burrill and Company, analysis based on publicly available data, 2009.

3/ Archstone. The Biopharmaceutical Sector's Impact on the U.S. Economy: Analysis at the National, State, and Local Levels. Washington, DC: Archstone Consulting, 2009.

4/ *Id*.

To foster continued economic growth and deliver the breakthroughs that will save lives and lower health care costs, our sector relies on public policies that encourage and protect pharmaceutical innovation. Patents in particular have proven essential to allow pharmaceutical companies and their investors to realize the benefits of their significant investments. They not only stimulate the early-stage discovery and development of new medicines, but also safeguard the sector's ability to carry out the lengthy and costly clinical investigations that are essential for ensuring that those medicines are safe and effective. The research-based pharmaceutical sector faces significant challenges to the discovery, development, testing, production, and ability to commercialize new medical treatments. Adequate protection of intellectual property is an economic prerequisite for continued medical advances against the most challenging and costly diseases.

Few advances in the last century have been as important to the preservation and enhancement of life as pharmaceutical innovations. According to University of Chicago economists, "[o]ver the last half century, improvements in health have been as valuable as all other sources of economic growth combined."[5/] New medicines have significantly reduced the socioeconomic burden of disease in the U.S. and around the world.[6/] These medical advances – driven by scientific research and creative genius – would have been impossible without a system of laws that provides the structure, stability, and opportunity for the needed investment.

Like innovators across the spectrum of American industries, pharmaceutical companies rely on patents to protect their inventions and provide the opportunity to recover their research investments. But patents are particularly important to pharmaceutical innovation given the research-intensive nature of this sector and the substantial investment required to discover and develop products that meet FDA approval requirements. Without patent protection, potential investors would see little prospect of a sufficient return on investment to offset the accompanying financial risk.[7/] It has been estimated that without patent protection, 65% of pharmaceutical products would never have been brought to market, while the average across all other industries was a mere 8%.[8/] It is well-established that patents are significantly more

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[5/] Kevin Murphy, Ph.D., and Robert Topel, Ph.D., Measuring the Gains from Medical Research: An Economic Approach (The University of Chicago Press, 2003).

[6/] For example, since 1980, the life expectancy for cancer patients has increased by about three years. It is estimated that new medicines account for 50-60% of the increases in survival rates since 1975. Frank Lichtenberg, *The Expanding Pharmaceutical Arsenal in the War on Cancer*, NBER Working Paper 10328, February, 2004. And death rates for cardiovascular disease fell a dramatic 31% between 1999 and 2006, according to a recent report by the American Heart Association. Will Dunham, *US Stroke, Heart Disease Death Rates Down Sharply*, Reuters, December 15, 2008.

[7/] Barfield, Claude, and Calfee, John. Biotechnology and the Patent System: Balancing Innovation and Property Rights. AEI Press, 2007.

[8/] Edwin Mansfield, *Patents and Innovation: An Empirical Study*, Management Science (Feb. 1986) at 173-181.

important for pharmaceutical firms than for other sectors of industry, in part due to the very high costs and lengthy time required to develop and bring to market new pharmaceutical products.[9/]

Research and development for new pharmaceuticals is unpredictable, requires immense investments of human and financial capital, and can take up to fifteen years of effort before a product is actually approved.[10/] These investments are made with no guarantee of FDA approval and no guarantee of return. In fact, only two in ten approved medicines ever produce revenues sufficient to recoup the average cost of drug development.[11/] Yet, once a pharmaceutical product has been developed, often it can easily be copied and produced. Patents protect inventions made in the course of R&D of a new medicine by giving the innovator the right to prevent the unauthorized use of the inventions for a defined term. The rights conveyed by a patent correspond to the invention – for example, a new drug molecule, a particular drug delivery system, new uses of a drug to treat different diseases, or a way the drug can be made. Thus, for example, depending on the nature of the patented invention, a patent may have a limited capacity to prevent the unauthorized copying of a new drug product. A patent provides proportionate, but not necessarily absolute, protection against copying.

Bringing new life-saving and life-improving products to people is the central role of our member companies. Because intellectual property is critical to carrying out this mission, PhRMA members particularly appreciate the efforts of the PTO to improve the patent prosecution process and strengthen the patent system.

II. Suggestions To Enhance The Quality Of Patents

The PTO requested comments on strategies and methods that may be employed by applicants and the PTO to enhance the quality of issued patents. The PTO's stated objective is to address patent process inefficiencies in a manner designed simultaneously to improve patent

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[9/] Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 JOURNAL OF INT'L ECONOMIC LAW 849-60 (2002).

[10/] In 1960, the average time to develop a new medicine was approximately eight years; by 2007, that figure had increased to between ten and fifteen years. *See Id.*; Joseph A. DiMasi, *New Drug Development in the U.S. from 1963-1999*, Vol. 69 No. 5, Clinical Pharmacology & Therapeutics 286, 292 (2001). At the same time, costs to bring new discoveries from laboratory to bedside have increased dramatically. A recent study from the Tufts University Center for the Study of Drug Development estimates the average cost of developing a new medicine (including the cost of capital) at more than $1.2 billion, in 2005 dollars. Joseph DiMasi and Henry Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, Managerial and Decision Economics, 2007, at 469-479. For every 5,000-10,000 compounds that enter the R&D pipeline, only 250 reach the pre-clinical stage, and of those, only five progress to clinical study in humans, and only one receives regulatory approval. PhRMA, *Drug Discovery and Development: Understanding the R&D Process* (2007), *available at* http://www.innovation.org/drug_discovery/objects/pdf/RD_Brochure.pdf.

[11/] John Vernon, et al., Health Economics Letters: Drug Development Costs When Financial Risk Is Measured Using The Fama–French Three-Factor Model, Health Economics (2009), *available at* www.interscience.wiley.com.

quality and reduce overall application pendency.[12/] In its Request for Comments, the PTO solicited comments on ways to improve several specific processes, including initial first Office Actions on the merits, responses to Office Actions, identification of prior art, and interviews. Below are suggestions, derived from PhRMA member companies' experiences, designed to improve patent quality in these areas.

1. The PTO Should Offer Incentives for Interviews and Allow More Flexibility with the Number of Office Actions

Examiner interviews play a critical role in fostering patent quality because they facilitate constructive dialogue between the examiner and the applicant, help the examiner to understand the claimed invention, and assist the applicant to appreciate the issues identified by the examiner. PhRMA agrees with the PTO that interviews should be conducted whenever they will facilitate resolving ambiguities and issues, or otherwise allow for a more effective examination.[13/] Accordingly, the PTO should make every effort to encourage interviews throughout the prosecution process, including before the first Office Action, after the first Office Action, and after a final Office Action.

With regard to interviews before the first Office Action, the PTO should continue to expand its First Action Interview Pilot Program in which an applicant is entitled to an interview with the examiner after the examiner has conducted a comprehensive prior art search but prior to the first Office Action on the merits.[14/] PhRMA joins the PTO in concluding that the patent process benefits when interaction between the applicant and the examiner is enhanced at the beginning of examination because patentability issues can potentially be resolved early when the applicant and the examiner discuss them one-on-one.[15/]

These benefits also can be achieved through interviews conducted both after the first Office Action and after a final Office Action. At the time of these interviews, the applicant will have reviewed the examiner's rejections and therefore will be in a position to discuss those rejections productively with the examiner. The PTO should consider enhancing incentives for interviews to be conducted after the first Office Action and after a final Office Action. The PTO's recent revision to the count system, which gives time-credit to examiners for initiating substantive interviews, makes measurable progress towards providing the proper incentives.[16/] The PTO should consider going further and developing a pilot program designed specifically to expand the frequency and use of interviews throughout the prosecution process. Facilitating dialogue between the applicant and the examiner after the first Office Action and after a final Office Action could reduce the time of application pendency by making the subsequent written

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[12/] 74 Fed. Reg. at 65094.

[13/] *Id*. at 65099.

[14/] Press Release, USPTO Expands Pilot Program to Reduce Pendency and Improve Patent Quality (Oct. 1, 2009), *available at* http://www.uspto.gov/news/pr/2009/09_20.jsp.

[15/] *Id*.

[16/] USPTO, *Changing the Patent Examiner Count System: New Rules for Docketing Requests for Continued Examination (RCEs), available at* www.uspto.gov/patents/rce_handling_in_new_count_system.doc.

submissions more responsive and appropriate. This may also help avoid the costs and resources associated with an appeal brief or at least result in a more focused appeal brief. These improved written submissions could ultimately reduce the burden on the examiner, to the benefit of the PTO and the applicant.

Because interviews may not be necessary in all cases, however, the PTO should consider a system in which interviews are not mandatory for applicants, but if an applicant requests an interview, the PTO must grant it. This would allow the applicant to prioritize among his or her applications as appropriate and avoid excessive burdens on both applicants and the PTO.

Because the quality of interviews also is important, the PTO should consider ways to ensure that the examiner is fully prepared and quality guidelines are followed. In the case of an interview prior to the first Office Action, the interview will be more constructive where, in advance of that meeting, the examiner has completed both a comprehensive prior art search and a review of that prior art. In the case of an interview conducted after the first Office Action or after a final Office Action, the interview will be more constructive where the examiner has provided a comprehensive first Office Action (and where appropriate subsequent Office Actions) on the merits. The PTO should consider using the expertise of the Quality Assurance Specialists, who play an important role in safeguarding quality.[17/] Involvement by these specialists in interviews could be beneficial to ensure that PTO quality guidelines are being followed. The PTO should consider giving applicants the right to request that a Quality Assurance Specialist attend an interview. In addition, the PTO should consider steps to ensure that examiners follow the PTO's guidelines for a thorough and complete initial prior art search and examination and a comprehensive first Office Action, and to measure examiner performance on that basis.

In conjunction with providing incentives for interviews and enhancing their quality, the PTO should change its practice in order to provide for two or more non-final Office Actions. If the applicant and the examiner are close to reaching agreement on allowable claims, an additional non-final Office Action would give an applicant the opportunity to amend the claims and obtain an allowance without the need to file a costly Request for Continued Examination ("RCE") or a continuation application. The filing of an RCE lengthens the pendency of an application, which can be avoided if issues are resolved quickly after the issuance of another non-final Office Action. The filing of a continuation application in these circumstances adds another application to the PTO's lengthening patent application queue, something which likely could be avoided or reduced by having more flexibility in Office Actions.

Promoting interviews and providing for additional Office Actions where necessary will increase communication between the applicant and the examiner, which will reduce pendency and increase patent quality. The provision of additional Office Actions should also be accompanied by continued PTO efforts to ensure comprehensive first Office Actions. It is important that the possibility of a second Office Action does not cause examiners to delay serious consideration of the case.

[17/] *See* Manual of Patent Examining Procedure § 1308.03 (8th ed. 2001) (Rev. 7, July 2008).

2. The PTO Should Consider Differentiating Applications

The PTO should avoid treating all patent applications alike when developing its procedures. Patent applications vary considerably in length, number of claims, and importance to the applicant. The PTO should consider differentiating among patent applications by adjusting the amount of time examiners are expected to spend conducting more burdensome examinations, and by adjusting fees and/or the timetable for review where appropriate. The quality of patent examinations are correlated closely with the amount of time an examiner devotes to an application, and recognition of complex applications should improve quality.

In this regard, the PTO should consider non-substantive rules for categorizing applications through objective criteria. For example, applications containing shorter specifications, fewer working examples, or a fewer number of total claims or independent claims could be eligible for a "fast track" review. If these eligibility requirements are met, the applicant could elect to pay a fee to have accelerated examination. The "fast track" option could also be available for applications deemed urgent or particularly important by an applicant. The "fast track" procedure would not entail a less rigorous examination and would have no effect on the presumption of validity of any issued patent. By providing a "fast track" option, the PTO could better align its resources and time with applicants' own priorities and resource allocation. This "fast track" option would not supplant the current accelerated examination program available under MPEP 708.02(a), but rather would provide another option for applicants.[18]

A "fast track" process would be consistent with the spirit of the PTO's successful Patent Prosecution Highway, in which an applicant that receives a favorable ruling from one nation's patent office on at least one claim in an application may request that the corresponding application filed in the United States advance out of turn for examination.[19/] Through this program, the PTO recognizes that not all applications are alike and some are ripe for a more streamlined examination.

3. The PTO Should Consider Additional Changes to the Count System

The count system should be adjusted (or replaced) so that it provides a more robust measurement of examiner productivity. Under the current count system, all applications are treated equally no matter how complicated or lengthy (and no matter the number of claims or references). The PTO's recent revision to the count system, which provides a greater amount of credit for the first Office Action on the merits and comparatively less credit for the first Office

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[18] *See* Manual of Patent Examining Procedure § 708.02(a) (8th ed. 2001) (Rev. 7, July 2008).

[19/] *See* "Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the European Patent Office based on Patent Cooperation Treaty Work Products," 1351 Off. Gaz. 208 (Feb. 23, 2010); *see also*, "Patent Prosecution Highway Pilot Program between the United States Patent and Trademark Office and the Japan Patent Office based on Patent Cooperation Treaty Work Products," 1351 Off. Gaz. 209 (Feb. 23, 2010).

Action after the filing of an RCE,[20/] is a step in the right direction; however, the system should be adjusted further. Just as patent attorneys spend widely varying amounts of time on different applications, so too should patent examiners, and the count system should recognize this. The count system should allow examiners to spend more time on complex applications by, for example, providing a greater amount of "credit" for applications that are lengthy, contain a large number of working examples or claims, or cite a large number of prior art references. This change would give the examiner adequate time to produce a more comprehensive first Office Action on the merits and conduct a more thorough review of the prior art, thereby enhancing the efficiency of patent prosecution and increasing patent quality.

The count system, along with restriction practice, creates perverse incentives for examiners to issue multiple-way restriction requirements for complex applications so that they can receive multiple counts for each divisional application that is filed. The count system should be amended so that examiners receive additional credit for examining complex applications without having to issue restriction requirements. For example, when composition of matter and therapeutic use claims are presented in the same application, the examiner usually issues a restriction requirement.[21/] If the composition of matter claims are found to be allowable, the examiner sometimes withdraws the original restriction requirement and rejoins the therapeutic use claims, which are subsequently examined for patentability.[22/] This process unnecessarily lengthens the pendency of the application. In other cases, the therapeutic use claims are not rejoined and the applicant is forced to file a divisional application in order to have these claims examined. The examination of a single application, as opposed to the examination of multiple divisional applications, would be more efficient and produce higher quality patents. The inefficiency of examining multiple applications directed to related inventions can be reduced by providing examiners with a greater amount of credit for applications that contain multiple claims which may otherwise be divided up into multiple applications.

4. The PTO Should Establish and Enforce Rigorous Patent Examination Training and Guidelines for Examiners

There are over 6,000 examiners at the PTO, with varied levels of experience.[23/] It would be helpful to have rigorous guidelines for examiners. The PTO's quality initiative for fiscal year 2010, which involves review of Office Actions for the purpose of providing individual examiner feedback and training,[24/] is a worthwhile task. Training could be improved further through initiatives such as encouraging mentoring and collaborative work on applications, making use of retired examiners as trainers, training examiners in areas such as negotiation and communication

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[20/] USPTO, *Changing the Patent Examiner Count System: New Rules for Docketing Requests for Continued Examination (RCEs), available at* www.uspto.gov/patents/rce_handling_in_new_count_system.doc.

[21/] *See* Manual of Patent Examining Procedure § 806.05(h) (8th ed. 2001) (Rev. 7, July 2008).

[22/] *See id.*

[23/] USPTO, *Performance and Accountability Report Fiscal Year 2009*, p. 11, *available at* http://www.uspto.gov/about/stratplan/ar/2009/2009annualreport.pdf.

[24/] 74 Fed. Reg. at 65097.

skills, and inviting practitioners (e.g., practitioners who are past examiners) or bar associations to educate new examiners on the roles of the patent attorneys and agents. Such steps would result in enhanced recognition of the best prior art and comprehensive first Office Actions on the merits, which would ultimately increase patent quality.

These efforts to strengthen examiner quality depend on the PTO improving retention of its most experienced examiners. Patent examination is a complex process. Examiners develop expertise in technical areas, and this leads to better quality examination and better control over the backlog of applications. The PTO should consider developing more attractive employee retention programs for examiners, including improved work-at-home and bonus programs. Job satisfaction also could be increased by better correlating the credit examiners receive with the amount of work required by a particular patent application as discussed above with regard to changes in the count system. Improved examiner retention should help the backlog and the quality of review.

5. The PTO Should Appreciate That Applicants Want To Assist Examiners But Are Constrained By The Inequitable Conduct Doctrine To Characterize Prior Art

Under the doctrine of inequitable conduct, a court can render an entire patent unenforceable based on a finding that the patentee withheld or misrepresented any material information with the intent to deceive the PTO. Courts have stated that the original purpose of the inequitable conduct doctrine was to prevent patentees from enforcing patents that were acquired by fraud.[25/] Over the years through case law, however, the courts have significantly weakened the requirements for proving inequitable conduct and strayed far from the important purpose of the doctrine. Using malleable and vague judicially created standards, the Court of Appeals for the Federal Circuit has upheld inequitable conduct findings based on litigation-inspired second guessing of minor mistakes made during patent prosecution that have no bearing on patent validity.[26/] Such cases make the application of the inequitable conduct doctrine highly unpredictable.[27/]

[25/] *See Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F. 3d 1357, 1365-66 (Fed. Cir. 2008), *cert. denied*, 2009 US LEXIS 1894 (Mar. 9, 2009).

[26/] For example, the Federal Circuit has twice held that improperly claiming "small entity status," which allows the patentee to make smaller maintenance fee payments relating to a patent, but which has no bearing on the patentability of an invention, can constitute inequitable conduct. *Nilssen v. Osram Sylvania, Inc.*, 504 F.3d 1223, 1231 (Fed. Cir. 2007); *Ulead Sys., Inc. v. Lex Computer & Mgmt. Corp.*, 351 F.3d 1139, 1146 (Fed. Cir. 2003). In addition, the Federal Circuit has held that the materiality standard can be met if false statements were made in a "petition to make special," a mechanism used only to accelerate review of a pending patent application. *See Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008) (citing *General Electro. Music Corp. v. Samick Music Corp.*, 19 F.3d 1405, 1411 (Fed. Cir. 1994)).

[27/] In 2004, the National Research Council of the National Academies of Science, after a thorough and independent analysis of the patent system, criticized the inequitable conduct

Former Under Secretary Dudas acknowledged that the unpredictability of the inequitable conduct doctrine "results in counterproductive behavior before the [PTO]" that reduces the quality of patent prosecution.[28/] He explained that the inequitable conduct doctrine creates an environment that discourages applicants from explaining their submissions, for fear of making a misrepresentation, and encourages applicants to disclose an excessive number of prior art references, for fear of omitting a material reference.[29/]

To the extent that the PTO is suggesting in its Federal Register notice that patent applicants should characterize prior art for the examiner, or otherwise lead the examiner to the "best art,"[30/] the PTO needs to appreciate the grave consequences[31/] this could have for applicants in later litigation through second-guessing of inadvertent mistakes or omissions. Any characterization of the art made by the applicant has the potential to be spun in litigation as

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doctrine as one of several "subjective elements of patent litigation" that require reform to "increase predictability of patent dispute outcomes and reduce the cost of litigation." National Research Council, *A Patent System for the 21st Century*, at 117-18 (2004). In 2008, Federal Circuit Judge Randall Rader criticized the inequitable conduct doctrine for creating a "litigation tactic" that "opens new avenues of discovery; impugns the integrity of the patentee, its counsel, and the patent itself; excludes the prosecuting attorney from trial participation (other than as a witness); and even offers the trial court a way to dispose of a case without the rigors of a claim construction and other complex patent doctrines." *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting) (*Aventis II*), *cert. denied*, 2009 US LEXIS 3144 (Apr. 27, 2009). In 2007, Federal Circuit Judge Pauline Newman lamented that the Federal Circuit was "encouraging unwarranted charges of inequitable conduct, spawning . . . opportunistic litigation." *McKesson Info. Solutions, Inc. v. Bridge Med., Inc.*, 487 F.3d 897, 926 (Fed. Cir. 2007) (Newman, J., dissenting). Indeed, Federal Circuit judges and commentators have referred to the prevalence of inequitable conduct charges as a "plague" on the patent system. *See, e.g.*, *Aventis II*, 525 F.3d at 1350 (Rader, J., dissenting); *McKesson*, 487 F.3d at 926-27 (Newman, J., dissenting); *Ferring B.V. v. Barr Labs., Inc.*, 437 F.3d 1181, 1196-97 (Fed. Cir. 2006) (Newman, J., dissenting); James E. Hanft & Stacey S. Kerns, *The Return of the Inequitable Conduct Plague: When "I Did Not Know" Unexpectedly Becomes "You Should Have Known,"* 19 NO. 2 INTELL. PROP. & TECH. L.J. 1 (2007); John A. O'Brien, *Inequitable Conduct—Is the Federal Circuit Reviving the "Plague" Of The Past?*, 884 PLI 467 (2006); Katherine Nolan-Stevaux, *Inequitable Conduct Claims in the 21st Century: Combating the Plague*, 20 BERKELEY TECH. L.J. 147 (2005).

[28/] *Patent Reform: The Future of American Innovation: Hearing Before the S. Judiciary Comm.*, 110th Cong. (June 6, 2007) (testimony of Jon W. Dudas, Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office).

[29/] *Id.*

[30/] *See* 74 Fed. Reg. at 65098 (noting the difficulties involved in locating the best prior art and indicating the quality of patent examination increases when applicants assist examiners in "identifying prior art information.")

[31/] Cf. *In re DDAVP Direct Purchaser Antitrust Litigation*, 585 F.3d 677, 691-92 (2d Cir. 2009) (holding that "purchaser Plaintiffs have standing to raise *Walker Process* [antitrust] claims for patents that are already unenforceable due to inequitable conduct").

material misrepresentation. Under current inequitable conduct law, this makes any contribution to the examination beyond filing known prior art, potentially high risk even if the characterization is essentially correct. The inequitable conduct doctrine could prevent PhRMA members from supporting or fully taking advantage of programs that require augmented disclosures and that in turn give rise to significant litigation risks. As a result, we cannot support any effort to require applicants to characterize the prior art beyond providing a list of the known material art.

The PTO should consider alternative ways to improve the quality of prior art considered by examiners. For example, examiners could be required to use the professional on-line search personnel located in the Technology Centers (i.e., Information Technology Resource Person ("ITRP")) and in the Scientific and Technical Information Center ("STIC") that are available to them for non-patent literature searching.[32/] Better use of these resources would help ensure that examiners identify the most relevant prior art and have sufficient time to review it. This would result in more comprehensive first Office Actions without placing additional burdens on applicants, burdens that are made greater in light of the inequitable conduct doctrine.

6. The PTO Should Continue to Upgrade its Technology

The PTO's Strategic Information Technology Plan for fiscal years 2007 to 2012 purports to implement plans for disaster recovery, an Enterprise Architecture (EA) to implement IT/IS strategies, IT Security, and e-Government.[33/] The PTO should continue to work on these efforts and apprise the public as to its progress. Due to changing needs, the PTO should consider providing updated progress reports on these issues on an annual basis rather than every five years. The PTO also should continue to improve its electronic filing system and EFS forms, which could significantly increase and improve efficiency for both the PTO and applicants.

The PTO also should work to unify international practice regarding electronic patent submissions. For example, the PTO should consider an e-filing format that is compatible with other international electronic filing systems such as EPOline®. More generally, the PTO should provide progress updates and describe the strides it has made or will make based on discussions with other patent offices about harmonizing technology, work sharing or other issues.

III. Conclusion

PhRMA appreciates the PTO's efforts to enhance the quality of patents and the opportunity to offer suggestions. PhRMA and its member companies are committed to helping the PTO find solutions to the many challenges it faces today and in the years to come.

[32/] *See* Manual of Patent Examining Procedure § 904.02 (8th ed. 2001) (Rev. 7, July 2008).

[33/] *See* USPTO, Office of the Chief Information Officer Strategic Information Technology Plan FY 2007 – FY 2012, *available at* www.uspto.gov/web/offices/cio/sitp/ocio_sitp_fy07.doc.