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U.S. Citizenship
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FILE: [REDACTED] Office: VERMONT SERVICE CENTER

Date: JUN 24 2005

IN RE: Petitioner: [REDACTED]
Beneficiary: [REDACTED]

PETITION: Immigrant Petition for Alien Worker as an Alien of Extraordinary Ability Pursuant to Section 203(b)(1)(A) of the Immigration and Nationality Act, 8 U.S.C. § 1153(b)(1)(A)

ON BEHALF OF PETITIONER:

[REDACTED]

INSTRUCTIONS:

This is the decision of the Administrative Appeals Office in your case. All documents have been returned to the office that originally decided your case. Any further inquiry must be made to that office.

Robert P. Wiemann, Director
Administrative Appeals Office

DISCUSSION: The employment-based immigrant visa petition was denied by the Director, Vermont Service Center, and is now before the Administrative Appeals Office on appeal. The appeal will be dismissed.

The petitioner seeks classification as an employment-based immigrant pursuant to section 203(b)(1)(A) of the Immigration and Nationality Act (the Act), 8 U.S.C. § 1153(b)(1)(A), as an alien of extraordinary ability in the sciences. The director determined the petitioner had not established the sustained national or international acclaim necessary to qualify for classification as an alien of extraordinary ability.

Section 203(b) of the Act states, in pertinent part, that:

(1) Priority Workers. -- Visas shall first be made available . . . to qualified immigrants who are aliens described in any of the following subparagraphs (A) through (C):

(A) Aliens with Extraordinary Ability. -- An alien is described in this subparagraph if --

(i) the alien has extraordinary ability in the sciences, arts, education, business, or athletics which has been demonstrated by sustained national or international acclaim and whose achievements have been recognized in the field through extensive documentation,

(ii) the alien seeks to enter the United States to continue work in the area of extraordinary ability, and

(iii) the alien's entry to the United States will substantially benefit prospectively the United States.

As used in this section, the term “extraordinary ability” means a level of expertise indicating that the individual is one of that small percentage who have risen to the very top of the field of endeavor. 8 C.F.R. § 204.5(h)(2). The specific requirements for supporting documents to establish that an alien has sustained national or international acclaim and recognition in his or her field of expertise are set forth in the regulation at 8 C.F.R. § 204.5(h)(3). The relevant criteria will be addressed below. It should be reiterated, however, that the petitioner must show that he has earned sustained national or international acclaim at the very top level.

This petition, filed on January 27, 2003, seeks to classify the petitioner as an alien with extraordinary ability in pharmacokinetics. At the time of filing, the petitioner was working as a “pharmacokinetics reviewer” in the Office of Clinical Pharmacology and Biopharmaceuticals (OCPB), Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA), U.S. Department of Health and Human Services.

The regulation at 8 C.F.R. § 204.5(h)(3) indicates that an alien can establish sustained national or international acclaim through evidence of a one-time achievement (that is, a major, international recognized award). Barring the alien’s receipt of such an award, the regulation outlines ten criteria, at least three of which must be satisfied for an alien to establish the sustained acclaim necessary to qualify as an alien of extraordinary ability. The petitioner has submitted evidence that, he claims, meets the following criteria.

Documentation of the alien's receipt of lesser nationally or internationally recognized prizes or awards for excellence in the field of endeavor.

We note here that the plain wording of this criterion requires “nationally or internationally recognized” prizes or awards for excellence in the field. The burden is on the petitioner to demonstrate the level of recognition and achievement associated with his awards.

The petitioner submitted two Certificates of Appreciation for podium presentations and a “Third Place Podium Presentation” award certificate issued by the petitioner’s superior, [REDACTED] Office Director, OCPB, CDER, FDA, U.S. Department of Health and Human Services, on “OCPB Science Day” in 2000 and 2002.

As a member of the Division of Pharmaceutical Evaluation II Exposure-Response Group, the petitioner received a “Team Excellence Award” issued by another superior, [REDACTED] Director, CDER, FDA, U.S. Department of Health and Human Services.

We note that the preceding awards are reflective of institutional recognition, rather than national or international recognition.

In 1999, while pursuing his Ph.D. at the University of Illinois at Chicago, the petitioner was selected to receive a “Van Doren Scholars” award. In respect to awards from universities and other learning institutions, Citizenship and Immigration Services (CIS) views academic awards as local or institutional honors rather than internationally recognized awards for the reason that they are limited to the individual school or institution presenting the awards. This criterion is intended to be restrictive and cannot be open to every individual who has received a scholarship or stipend from his university. Furthermore, there is no indication that petitioner’s award was presented for excellence in his field rather than general scholastic achievements and other traits deemed praiseworthy by his university. University study is not a field of endeavor, but, rather, training for future employment in a field of endeavor. We cannot artificially restrict the petitioner’s field to exclude all those scientists who had long since completed their educational training and therefore did not compete for such an award.

In this case, the petitioner has not shown that his awards are widely recognized beyond the organization that presented them.

Documentation of the alien's membership in associations in the field for which classification is sought, which require outstanding achievements of their members, as judged by recognized national or international experts in their disciplines or fields.

In order to demonstrate that membership in an association meets this criterion, the petitioner must show that the association requires outstanding achievement as an essential condition for admission to membership. Membership requirements based on employment or activity in a given field, minimum education or experience, standardized test scores, grade point average, recommendations by colleagues or current members, or payment of dues, do not satisfy this criterion as such requirements do not constitute outstanding achievements. In addition, it is clear from the regulatory language that members must be selected at the

national or international level, rather than the local or regional level. Finally, the overall prestige of a given association is not determinative; the issue here is membership requirements rather than the association's overall reputation.

The petitioner submitted evidence of his membership in the American Association of Pharmaceutical Scientists (AAPS) and the Korean-American Pharmaceutical Scientists Association (KAPSA). According to information provided by the petitioner from the AAPS' website, "[m]embership is open to any individual who supports the objectives of the association and is willing to contribute to the achievement of these objectives. As such, members can come from industry, academia, government, and private institutions." The record contains no evidence of the bylaws or official admission requirements for KAPSA.

The evidence presented by the petitioner fails to demonstrate that his membership in either association required outstanding achievement or that he was evaluated by national or international experts in consideration of his membership. The record contains no indication that the preceding associations require outstanding achievement of their members in the same manner as highly exclusive associations such as the U.S. National Academy of Sciences.

Published materials about the alien in professional or major trade publications or other major media, relating to the alien's work in the field for which classification is sought. Such evidence shall include the title, date, and author of the material, and any necessary translation.

In general, in order for published material to meet this criterion, it must be primarily about the petitioner and, as stated in the regulations, be printed in professional or major trade publications or other major media. To qualify as major media, the publication should have significant national distribution.

Counsel initially argued that cited references to articles authored by the petitioner would satisfy this criterion. Articles which cite the petitioner's work are primarily about the author's own work, not the petitioner's work. As such, they cannot be considered qualifying published material about the petitioner's work. We cannot ignore that the articles citing the petitioner's work similarly referenced numerous other authors. In the petitioner's field, it is the nature of research work to build upon work that has gone before. In some instances, prior work is expanded upon or supported. In other instances, prior work is superseded by the findings in current research work. In either case, the current researcher normally cites the work of the prior researchers. Clearly this is not the same thing as published material written about an individual's work in the field. This type of material does not discuss the merits of an individual's work, the individual's standing in the field, or any significant impact that his or her work has had on work in the field. Citations of the petitioner's work will be addressed under a separate criterion.

Evidence of the alien's participation, either individually or on a panel, as a judge of the work of others in the same or an allied field of specification for which classification is sought.

The petitioner submitted evidence showing that his work as a "pharmacokinetics reviewer" at the FDA involves evaluating the safety and effectiveness of drug treatments and therapies. [REDACTED] states: "[The petitioner's] regular duties include evaluation of the study plans for new drug candidates on U.S. subjects."

On appeal, counsel argues that two cholesterol-lowering drug applications processed by the petitioner in his capacity as a pharmacokinetics reviewer for FDA's OCPB constitute qualifying evidence under this criterion. In an occupation where "judging" the work of others is an inherent duty of the occupation, such as an instructor, teacher, professor or editor, simply performing one's job related duties demonstrates competency, and is not evidence of national or international acclaim.¹ The two New Drug Application (NDA) reviews provided by the petitioner indicate that his "Team Leader" had to sign-off and authorize the petitioner's findings.

As previously noted, the regulation at 8 C.F.R. § 204.5(h)(3) provides that "a petition for an alien of extraordinary ability must be accompanied by evidence that the alien has sustained national or international acclaim and that his or her achievements have been recognized in the field of expertise." Evidence of the petitioner's participation as a judge must be evaluated in terms of these requirements. In this instance, we note that the petitioner is clearly not the final authority for releasing NDA reviews and that conducting such reviews is a routine duty inherent to his position within the FDA's OCPB. For these reasons, we cannot conclude that conducting such reviews elevates the petitioner above almost all others in his field at the national or international level or demonstrates his widespread acclaim.

The petitioner also submitted a letter from the Executive Editor-in-Chief of *Life Sciences* indicating that the petitioner reviewed a single manuscript for that journal.²

We note here that peer review of manuscripts is a routine element of the process by which articles are selected for publication in scholarly journals. Occasional participation in peer review of this kind does not automatically demonstrate that the petitioner has earned sustained national or international acclaim at the very top of his field. Reviewing manuscripts is recognized as a professional obligation of scientists who publish themselves in scientific journals. Normally a journal's editorial staff will enlist the assistance of numerous professionals in the field who agree to review submitted papers. It is common for a publication to ask several reviewers to review a manuscript and to offer comments. The publication may accept or reject any reviewer's comments in determining whether to publish or reject submitted papers.

Without evidence that sets the petitioner apart from others in his field, such as evidence that he has peer-reviewed an unusually large number of manuscripts for publication in various scientific journals, received multiple independent requests for his services from a substantial number of journals, or served in an editorial position for a distinguished journal (in the same manner as, for example, [REDACTED] Professor of Pharmacokinetics, Seoul National University, who states that he serves on the editorial boards of two international journals), we cannot conclude that the petitioner meets this criterion.

Evidence of the alien's original scientific, scholarly, artistic, athletic, or business-related contributions of major significance in the field.

¹ This is true with all duties inherent to an occupation. For example, publication is inherent to researchers. Thus, the mere publication of scholarly articles cannot demonstrate national acclaim. The petitioner must demonstrate that the articles have garnered national attention, for example, by being widely cited.

² The July 31, 2001 letter notes that the petitioner reviewed the original version of a manuscript submitted to the journal and requests that the petitioner now evaluate the revised version of that same manuscript.

The petitioner submitted five letters in support of the petition. [REDACTED] of OCPB states:

[The petitioner] has several years of research experience in the area of transporters. [The petitioner] made outstanding contributions to elucidation potential of transporters as sources of drug-drug interaction, food-drug interaction, or variability in pharmacokinetics and pharmacodynamics. . . . [The petitioner's] cutting edge research demonstrated that transporters are one of the major factors in drug absorption and disposition. Also, modulators of transporter can affect pharmacokinetics of a co-administered drug. He has extended his expertise through transporter working group in the Office. [The petitioner] has evaluated the impact of continuously emerging transporter science on the drug development and regulatory decision.

[REDACTED] Director, Division of Pharmaceutical Evaluation II, OCPB, CDER, FDA, U.S. Department of Health and Human Services, states that the petitioner is "well trained in the area of human pharmacokinetics, pharmacodynamics, drug metabolism, biopharmaceutics, statistical methodologies, and pharmaceutical analysis, which comprises the most visible and essential disciplines for the drug development and evaluation process." [REDACTED] further states: "Since [the petitioner's] appointment as a primary pharmacokinetic reviewer, [the petitioner] has made exceptional contributions to the review and regulatory mission of the FDA."

[REDACTED] Team Leader, Pulmonary and Allergic Drug Products, Division of Pharmaceutical Evaluation II, OCPB, CDER, FDA, U.S. Department of Health and Human Services, states:

[The petitioner's] extensive training in pharmacokinetics, drug metabolism, physiology, pharmaceutics and molecular biology has provided him with an excellent knowledge base for his current position at CDER, FDA. Since his arrival at FDA I have had the pleasure of working with [the petitioner] [The petitioner's] reviews of sponsor submissions have been impressive and outstanding. [The petitioner] also never hesitates to invest long hours in order to meet deadlines and fulfills the tasks assigned to him in an exemplary manner.

The letters of support indicate that the petitioner has performed admirably in his division within the OCPB, but his ability to significantly impact the pharmaceutical industry in general has not been adequately demonstrated. The issue here is not the petitioner's extensive training or dedication to his work, but, rather, whether any of his past research accomplishments would qualify as a contribution of "major significance" in pharmacokinetics.

[REDACTED] further states: "I am also very impressed with [the petitioner's] current research at CDER, FDA, involving modeling of disease progression. . . . The results of his research when published will surely be outstanding to kinetics of drug effect." The record, however, contains no evidence showing that the results of the petitioner's research pertaining to the modeling of disease progression were published as of the petitioner's filing date. A petitioner must establish eligibility at the time of filing. *See Matter of Katigbak*, 14 I&N Dec. 45 (Comm. 1971). The assertion that the petitioner's research results hold future promise is not adequate to establish that his findings are already nationally or internationally acclaimed as a major contribution.

██████████ indicates that he was the petitioner's "thesis advisor" at Seoul National University. ██████████ states: "[The petitioner's] research has been invited for publication in some of the top journals in his field such as *Pharmaceutical Research*, *Clinical Pharmacology and Therapeutics*, and *International Journal of Clinical Pharmacology and Therapeutics*" We accept that petitioner's published work has yielded some useful and valid results; however, it is apparent that any journal article, in order to be accepted for publication or presentation, must offer new and useful information to the pool of knowledge. It does not follow that every scientist whose scholarly research is accepted for publication or presentation has made a major contribution in his field.

Many of the individuals offering letters of support cite the petitioner's published articles as evidence of his original contributions. Published work, however, falls under the next criterion, a criterion that we find the evidence in this case adequately satisfies. Here it should be emphasized that the regulatory criteria are separate and distinct from one another. Because separate criteria exist for published work and contributions, Citizenship and Immigration Services (CIS) clearly does not view the two as being interchangeable. If evidence sufficient to meet one criterion mandated a finding that an alien met another criterion, the requirement that an alien meet at least three criteria would be meaningless. We will fully address the petitioner's published works and citations under the next criterion.

██████████ Chief, Unit of Molecular Biology, Laboratory of Membrane Biochemistry and Biophysics, National Institutes of Health, states:

[The petitioner] has . . . served the scientific FDA working group of *in vitro* metabolism and transporters since January 2001. The FDA team has evaluated the area of drug metabolism and transporters critically important in drug development. The first topic was the inhibitory monoclonal antibodies to human cytochrome P450 enzymes as a new candidate for drug discovery, which I have been one of the core researchers during the development at NIH. The FDA working group critically evaluated the results of 10-year study at NIH to prepare guidelines for American pharmaceutical companies.

On appeal, counsel describes ██████████ as an "outside expert," noting that ██████████ is not a collaborator, supervisor, or mentor of [the petitioner]." Nevertheless, we cannot ignore that both he and the petitioner were jointly associated with the above project – the petitioner as an FDA evaluator and ██████████ as a "core researcher." There is no indication that ██████████ was aware of the petitioner's work or standing in the field prior to their joint involvement with the NIH study.

The petitioner's witnesses consist of three superiors from the OCPB, his master's thesis advisor, and ██████████ who is directly associated with a NIH project evaluated by the petitioner's team. These individuals discuss the petitioner's scientific expertise and current job responsibilities, but they offer little or no information regarding how the petitioner's specific individual research contributions have significantly impacted the greater field. With regard to the personal recommendation of individuals from institutions where the petitioner has studied and worked, the source of the recommendations is a highly relevant consideration. These letters are not first-hand evidence that the petitioner has earned sustained acclaim for his contributions outside of his affiliated educational and governmental institutions. If the petitioner's reputation is mostly limited to those institutions, then he has not achieved national or international acclaim, regardless of

the expertise of his witnesses. An individual with sustained national or international acclaim should be able to produce ample unsolicited materials reflecting that acclaim. Without extensive documentation showing that the petitioner's findings have been unusually influential or highly acclaimed throughout the greater field, we cannot conclude that his work rises to the level of a contribution of *major* significance.

Evidence of the alien's authorship of scholarly articles in the field, in professional or major trade publications or other major media.

The petitioner submitted evidence of his authorship of articles appearing in publications such as *International Journal of Clinical Pharmacology and Therapeutics*, *Pharmaceutical Research*, and *Journal of Laboratory and Clinical Medicine*. The petitioner also submitted citation indices showing that his articles have been cited by other researchers. When judging the influence and impact that the petitioner's published work has had, the very act of publication is not as reliable a gauge as is the citation history of the published works. Publication alone may serve as evidence of originality, but it is difficult to conclude that a published article is important or influential if there is little evidence that other researchers have relied upon the petitioner's findings. In this case, however, the number of cites to the petitioner's articles demonstrates an acceptable degree of interest in, and reliance on, his work. Based on the citation history of his published work, we find that the petitioner minimally satisfies this criterion.

Evidence that the alien has performed in a leading or critical role for organizations or establishments that have a distinguished reputation.

[REDACTED] states: "Currently [the petitioner] is one of only five pharmacokinetic reviewers supporting the Division of Metabolic and Endocrine Drug Products (DMEDP) [of OCPB]." We cannot ignore that the petitioner's role, when compared to that of his three witnesses from OCPB, was that of a subordinate. The record contains no evidence showing the extent to which the petitioner has exercised substantial control over personnel or research decisions executed on behalf of OCPB. Nor is there any indication of the relative importance of the petitioner's role to that of the four other pharmacokinetic reviewers in his division, or pharmacokinetic reviewers from throughout the FDA for that matter.

For the above reasons, we find that the petitioner's evidence falls short of establishing that he has performed in a leading or critical role for a distinguished organization, or that his involvement has earned him sustained national or international acclaim.

In this case, we find that the evidence satisfies only one of the regulatory criteria at 8 C.F.R. § 204.5(h)(3).

Review of the record does not establish that the petitioner has distinguished himself to such an extent that he may be said to have achieved sustained national or international acclaim or to be within the small percentage at the very top of his field. The evidence is not persuasive that the petitioner's achievements set him significantly above almost all others in his field at the national or international level. Therefore, the petitioner has not established eligibility pursuant to section 203(b)(1)(A) of the Act and the petition may not be approved.

The burden of proof in visa petition proceedings remains entirely with the petitioner. Section 291 of the Act, 8 U.S.C. § 1361. Here, the petitioner has not sustained that burden. Accordingly, the appeal will be dismissed.



ORDER: The appeal is dismissed.