U.S. Citizenship and Immigration Services

Non-Precedent Decision of the Administrative Appeals Office

MATTER OF R-P-

DATE: AUG. 25, 2017

APPEAL OF NEBRASKA SERVICE CENTER DECISION

PETITION: FORM I-140, IMMIGRANT PETITION FOR ALIEN WORKER

The Petitioner, a medical scientist, seeks classification as an individual of extraordinary ability in the sciences. *See* Immigration and Nationality Act (the Act) section 203(b)(1)(A), 8 U.S.C. § 1153(b)(1)(A). This first preference classification makes immigrant visas available to those who can demonstrate their extraordinary ability through sustained national or international acclaim and whose achievements have been recognized in their field through extensive documentation.

The Director of the Nebraska Service Center denied the Form I-140, Immigrant Petition for Alien Worker, concluding that the Petitioner had satisfied only one of the initial evidentiary criteria, of which he must meet at least three.

On appeal, the Petitioner submits a brief and additional evidence. He contends that he meets six of the required criteria and possesses the required level of expertise for this classification.

Upon *de novo* review, we will dismiss the appeal.

I. LAW

Section 203(b)(1)(A) of the Act states:

> Aliens with extraordinary ability. -- An alien is described in this subparagraph if –
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> (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,
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> (ii) the alien seeks to enter the United States to continue work in the area of extraordinary ability, and
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> (iii) the alien's entry into the United States will substantially benefit prospectively the United States.

The term "extraordinary ability" refers only to those individuals in "that small percentage who have risen to the very top of the field of endeavor." 8 C.F.R. § 204.5(h)(2). The implementing regulation at 8 C.F.R. § 204.5(h)(3) sets forth two options for satisfying this classification's initial evidence requirements. First, a petitioner can demonstrate a one-time achievement (that is a major, internationally recognized award). Alternately, he or she must provide evidence that meets at least three of the criteria listed at 8 C.F.R. § 204.5(h)(3)(i)-(x) (including items such as awards, published material in certain media, and scholarly articles).

Where a petitioner meets these initial evidence requirements, we then consider the totality of the material provided in a final merits determination and assess whether the record shows sustained national or international acclaim and demonstrates that the individual is among the small percentage at the very top of the field of endeavor. *See Kazarian v. USCIS*, 596 F.3d 1115 (9th Cir. 2010) (discussing a two-part review where the documentation is first counted and then, if fulfilling the required number of criteria, considered in the context of a final merits determination); *see also Visinscaia v. Beers*, 4 F. Supp. 3d 126, 131-32 (D.D.C. 2013); *Rijal v. USCIS*, 772 F. Supp. 2d 1339 (W.D. Wash. 2011). This two-step analysis is consistent with our holding that the "truth is to be determined not by the quantity of evidence alone but by its quality," as well as the principle that we examine "each piece of evidence for relevance, probative value, and credibility, both individually and within the context of the totality of the evidence, to determine whether the fact to be proven is probably true." *Matter of Chawathe*, 25 I&N Dec. 369, 376 (AAO 2010).

II. ANALYSIS

The Petitioner received his medical degree in 2000 from the [redacted] in Croatia. He then earned a master's degree in health services management from the [redacted] in 2006. He subsequently joined [redacted] a contract research organization providing outsourced clinical development services to the biotechnology and pharmaceutical industries. The record includes a company prospectus describing how [redacted] has performed approximately 3300 clinical trials worldwide on six continents. The Petitioner currently serves as a clinical team manager where his duties include evaluating and selecting potential trial sites; initiating the clinical trial at investigative sites, instructing site personnel including physicians and medical scientists on the proper conduct of clinical trials; observing and conducting performance checks on site, including verifying serious adverse event reporting and reviewing and confirming the accuracy of collected data; determining the efficacy of the clinical trial; and, assessing the medication and treatment.

As the Petitioner has not indicated or established that he has received a major, internationally recognized award, he must satisfy at least three of the alternate regulatory criteria at 8 C.F.R. §§ 204.5(h)(3)(i)-(x). In denying the Petition, the Director found that that the Petitioner met the judging criterion under 8 C.F.R. § 204.5(h)(3)(iv). On appeal, the Petitioner maintains that he also meets the following five criteria: published material,[1] original contributions,[2] authorship of

[1] 8 C.F.R. § 204.5(h)(3)(iii).

scholarly articles,[3] display at artistic exhibitions or showcases,[4] and leading or critical role[5]. We have reviewed all of the evidence in the record of proceedings, and it does not support a finding that the Petitioner meets the plain language requirements of at least three criteria.

A. Evidentiary Criteria

> *Published material 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.* 8 C.F.R. § 204.5(h)(3)(iii).

The Petitioner claims eligibility under this criteria based upon the publication of an article entitled ' published in 2015 in The article was subsequently published on the online version of the journal in 2016. This article was authored by the Petitioner and five co-authors and describes the culmination of the team's research developing computational tools for improving the safety and efficacy of clinical trials. While we do not dispute that is a form of major media, the article referenced is not about the Petitioner; rather, it is a peer-reviewed journal article reporting his findings.[6] The plain language of the regulation requires that the items be "about" the Petitioner, relating to his work. Articles that do not discuss the Petitioner are not "about" him. Similarly, the Petitioner references two symposia presentations presented at the and the that he authored. The evidence does not show that these presentations are about the Petitioner, or that the symposia where they were presented are either major trade publications or other major media. As such, we find that the Petitioner has not met this 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.* 8 C.F.R. § 204.5(h)(3)(iv).

The Petitioner also asserts that his experience as a clinical team manager for qualifies under this criterion. The Petitioner states that his duties include evaluating hospitals, physicians, and medical personnel in their performance in clinical trial protocols, and serving as the "sole arbiter" of whether the clinical trial will be utilized in assessing the medication or treatment. He also notes that

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[2] 8 C.F.R. § 204.5(h)(3)(v).
[3] 8 C.F.R. § 204.5(h)(3)(vi).
[4] 8 C.F.R. § 204.5(h)(3)(vii).
[5] 8 C.F.R. § 204.5(h)(3)(viii).
[6] The regulations contain a separate criterion regarding scholarly articles. 8 C.F.R. § 204.5(h)(3)(vi). Consistent with the regulatory requirement that a petitioner meet at least three separate criteria, we will generally not consider evidence relating to the scholarly articles criterion to satisfy this one.

he oversees his staff of medical scientists who monitor each trial location including evaluating their job performance.

Serving as a manager where part of one's job duties includes evaluating other professionals in the exercise of his or her duties does not equate to participation as a judge of the work of others in the field. The phrase "a judge" implies a formal designation in a judging capacity, either on a panel or individually as specified pursuant to the regulation at 8 C.F.R. § 204.5(h)(3)(iv). The regulation cannot be read to include every informal instance of evaluating subordinate employees. The record does not include evidence demonstrating that the Petitioner actually served "as a judge of the work of others." Incidental evaluation responsibilities inherent to a managerial position do not establish that the Petitioner served in an official capacity, either individually or on a panel, as "a judge" of the work of others. Accordingly, while the Director found that the Petitioner satisfied this criterion, we disagree with that finding.

> *Evidence of the alien's original scientific, scholarly, artistic, athletic, or business-related contributions of major significance in the field.* 8 C.F.R. § 204.5(h)(3)(v).

The Petitioner contends that he has made original contributions of major significance to the field through his clinical trial leadership for his presentations at symposia and conferences, and his work contributing to the development of an automated clinical trials system. The Director acknowledged this evidence, but found that it was not sufficient to demonstrate that the Petitioner's work constituted original contributions of major significance in the field.

On appeal, the Petitioner maintains that that a number of experts and colleagues have offered testimony regarding his contributions of major significance.[7] For example, a senior clinical research associate with described how the Petitioner's "experience and knowledge makes him a valuable mentor and team lead." director of cardiomyopathy at the Croatia, noted that the Petitioner's "knowledge of ethical and scientific quality standards and rights" was "instrumental" to his career. associate clinical project manager at stated that she worked with the Petitioner on a clinical trial aimed at treating children with seizure disorders. She described how the Petitioner's "skill and expertise" "contributed to the success of the study." While the letters commend the Petitioner for his expertise in managing clinical trials they lack specificity regarding how his achievements have affected the field or how the asserted achievements are being used or reproduced within the field. While such letters are important in providing details about the Petitioner's role in various clinical trials, they do not establish his impact beyond his immediate circle of colleagues.

The Petitioner also maintains that his work relating to the development of a remote monitoring plan designed to automate the clinical trials process should be considered a contribution of major

[7] While we discuss only a sampling of these letters, we have reviewed and considered each one.

significance. He does not provide details explaining the plan, or how it has impacted the field of clinical trials.

Several of the letters also discuss the trial automation tool. chairman of the department of mathematics at the wrote that the Petitioner collaborated with his research team in 2011 to develop an automated tool used in clinical trials that would "detect and prevent discrepancies and mistakes as early as possible." He explained that their proposed model, known as is the "first step in achieving the automated tool," and that the Petitioner was an "essential architect" in its development. Similarly, associate professor at in Brazil, commented that the Petitioner's insight helped him develop the foundations for the construction of a clinical trial assistant. He stated that the Petitioner "greatly simplified the task of running a trial by utilizing a clinical trial assistant to automate some analysis and compliance checks informing and even predicting when some deviation could occur." He attested that the Petitioner's insights "led to the success of our work by helping us further develop and refine our languages building the foundations for the construction of the clinical trial assistant." While these letters discuss the "clinical trial assistant," they do not explain whether the tool was ultimately developed for commercial use, or whether it is now being implemented in the clinical trials process. Without additional detail explaining the Petitioner's accomplishments relating to this tool, the record does not adequately demonstrate that this work has made a significant impact on his field.

On appeal, the Petitioner asserts that the fact that this work was introduced at an international conference and published in the conference proceedings along with numerous other participants, contributes to his eligibility under this criterion. Many professional fields regularly hold conferences and symposia to present new work, to discuss new findings, and to network with other professionals. Professional associations, businesses, educational institutions, and government agencies promote and sponsor these conferences. Participation in these events, however, does not necessarily reflect an original contribution of major significance in the field. The Petitioner has not demonstrated the impact of his findings after dissemination to the field at the conferences.

Finally, the evidence does not demonstrate that the Petitioner has made contributions of major significance to the field as a whole; rather, his work is limited to advancing the clinical trials initiatives of his employer, The plain language of the regulation at 8 C.F.R. § 204.5(h)(3)(v) requires that the contributions be "of major significance in the field" rather than limited to one's immediate employer and a sampling of its customers or clients. *See Visinscaia v. Beers*, 4 F. Supp. 3d at 134-35 (upholding a finding that a ballroom dancer had not met this criterion because she did not corroborate her impact in the field as a whole). Here, the record does not include documentary evidence showing the widespread commercial or industrial implementation of the Petitioner's work, that it has been seminal, or that it otherwise equates to an original contribution of major significance in the field.

Evidence of the alien's authorship of scholarly articles in the field, in professional or major trade publications or other major media. 8 C.F.R. § 204.5(h)(3)(vi).

The Petitioner submitted evidence of his authorship of the article entitled ' published in in 2015. This evidence satisfies the requirements of this criterion.

> *Evidence of the display of the alien's work in the field at artistic exhibitions or showcases. 8 C.F.R. § 204.5(h)(3)(vii).*

The Petitioner indicates that the display of his work at scientific conferences and conference proceedings meets this criterion. Scientific conferences facilitate the dissemination of research among scientists and are not the same as artistic showcases or exhibitions designed to showcase artwork, as required by this criterion, nor is the Petitioner's work artistic in nature. Accordingly, the Petitioner has not met this criterion.[8]

> *Evidence that the alien has performed in a leading or critical role for organizations or establishments that have a distinguished reputation.* 8 C.F.R. § 204.5(h)(3)(viii).

The Director determined that the Petitioner did not establish that his role for was leading or critical. On appeal, the Petitioner contends that he performs in a leading and critical role for "where he leads advanced, high-stakes, multi-million dollar clinical trials of breakthrough medications and treatments on human test subjects." The record includes a letter from senior manager of clinical operations for who stated that the Petitioner "fills a critical need in our organization." She maintains that the Petitioner's role "contributes to the safety and well-being of study subjects who are treated on the clinical trials that [the Petitioner] manages."

In general, a leading role is evidenced from the role itself, and a critical role is one in which a petitioner was responsible for the success or standing of the organization or establishment. The letter does not specify how the Petitioner's role fits into the hierarchy of the organization to show that it is a leading role. Further, while stated that the Petitioner has "a broad range of therapeutic expertise that few others in his role have," she does not clarify how the Petitioner's work is critical to the success and standing of the organization, or suggest the manner in which the Petitioner's work has resulted in a measurable level of success for The company literature contained in the record indicates that the company operates "on six continents across 13 time zones" and employs more than 12,000 employees. The evidence does not demonstrate when he assumed the role of clinical trial manager, how his role differentiates him from the numerous other clinical trial managers working for around the world, what percentage of trials he oversees,[9] or how the organization has progressed since the Petitioner began working there.

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[8] Conference presentations are typically published in conference proceedings, serve the same purpose as scholarly articles in journals, and, therefore, generally fall under the scholarly articles criterion. We note that the Petitioner's initial brief included evidence of conference proceedings under the scholarly articles criterion at 8 C.F.R. § 204.5(h)(3)(vi).

[9] The Petitioner has provided conflicting information regarding the number of clinical trials that he has led. In the RFE response, he claimed that he has "led hundreds of trials;" yet, in the initial filing, he states that he "has led dozens of clinical trials," and on appeal, he states that he has "conducted 50 plus clinical investigations." Regardless, he has not

On appeal, the Petitioner contends that the record includes letters of support from employees establishing the leading or critical role that he plays for the organization. For example, a senior clinical research associate for describes how the Petitioner "expertly supervises" her team and indicates that his "knowledge of ethical and scientific quality standards and rights, safety, and well-being of patients involved is remarkable." Similarly, global project director for writes that the "vast knowledge and distinguished expertise of clinical research goes far beyond the average skills" of his peers, and that he "plays a crucial role in important clinical research studies and his projects would be seriously impaired without his invaluable contribution." While complementary of the Petitioner's skill in leading clinical trials, these letters fall short of specifying how the Petitioner contributed to the overall organization in a way that is significant to the organization's outcome. *See Visinscaia*, 4 F. Supp. 3d at 135.

Overall, the letters do not demonstrate how the Petitioner served in a leadership role for the entire organization or establishment, nor do they demonstrate how the success of the organization or establishment itself is attributable to any critical role the Petitioner performed. The letters primarily contain unsupported assertions that the Petitioner's role was critical without sufficient explanation. Merely repeating the language of the statute or regulations does not satisfy the Petitioner's burden of proof. *See Fedin Bros. Co., Ltd. v. Sava*, 724 F. Supp. 1103, 1108 (E.D.N.Y. 1989), *aff'd*, 905 F. 2d 41 (2d. Cir. 1990); *Avyr Associates, Inc. v. Meissner*, 1997 WL 188942 at *5 (S.D.N.Y.).

Furthermore, the record does not sufficiently establish that possesses a distinguished reputation consistent with this regulatory criterion. While the Petitioner claims that, in 2015, was named clinical company of the year for the of the year for the second year in a row, the record does not include evidence of such accolades, or explain their significance. USCIS need not accept primarily conclusory assertions. *See 1756, Inc. v. The Attorney General of the United States*, 745 F. Supp. 9, 17 (D.C. Dist. 1990).

B. Summary

As explained above, the record only satisfies one of the regulatory criteria. As a result, the Petitioner has not submitted the required initial evidence of either a one-time achievement or documents that meet at least three of the ten criteria listed at 8 C.F.R. §§ 204.5(h)(3)(i)-(x).

Had the Petitioner satisfied at least three evidentiary categories, the next step would be a final merits determination that considers all of evidence in the context of whether or not the Petitioner has demonstrated 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," that the individual "has sustained national or international acclaim, and that his or her achievements have been recognized in the field of expertise." 8 C.F.R. § 204.5(h)(2), (3); *see also Kazarian*, 596 F.3d at 1119-20. Although we need not provide the type of final merits determination referenced in *Kazarian*, a review of the record in

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provided evidence explaining the specific impact that his clinical trial leadership has had on the overall organization.

the aggregate supports a finding that the Petitioner has not established the level of expertise required for the classification sought. Specifically, while the Petitioner has documented success leading clinical trials for his employer, along with publication of a peer-reviewed article, the evidence does not sufficiently demonstrate that he is in the small percentage at the top of the field or show the sustained national or international acclaim required for this highly restrictive classification. Nor does the record include extensive documentation showing recognition of the Petitioner's achievements in the field.

III. CONCLUSION

The Petitioner has not demonstrated that he qualifies as an individual of extraordinary ability under section 203(b)(1)(A) of the Act. Accordingly, he has not established eligibility for the immigration benefit sought.

ORDER: The appeal is dismissed.

Cite as *Matter of R-P-* ID# 551639 (AAO Aug. 25, 2017)