



**U.S. Citizenship  
and Immigration  
Services**

**Non-Precedent Decision of the  
Administrative Appeals Office**

MATTER OF S-S-

DATE: JUNE 4, 2019

APPEAL OF NEBRASKA SERVICE CENTER DECISION

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

The Petitioner, a senior director in project management for a pharmaceutical company, seeks classification as an individual of extraordinary ability. *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 shown that he met three of the ten initial evidentiary criteria but that he did not establish eligibility in the final merits analysis.

On appeal, the Petitioner submits additional evidence and contends that he qualifies as an individual of extraordinary ability.

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

**I. LAW**

Section 203(b)(1)(A) of the Act makes visas available to immigrants with extraordinary ability 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 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). Alternatively, he or she must provide documentation that meets at least three of the ten categories of evidence listed at 8 C.F.R. § 204.5(h)(3)(i)-(x) (including items such as awards, memberships, and published material in certain media).

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

As that Petitioner has not established that he has received a major, internationally recognized award, he must satisfy at least three of the ten criteria at 8 C.F.R. § 204.5(h)(3)(i)-(x).

### A. Evidentiary Criteria

The Director held that the Petitioner met the criteria for judging under 8 C.F.R. § 204.5(h)(3)(iv), scholarly articles under 8 C.F.R. § 204.5(h)(3)(vi), and high salary under 8 C.F.R. § 204.5(h)(3)(ix). Because he met three of the required criteria, the Director conducted a final merits determination and concluded that the record did not establish that the Petitioner had risen to the very top of the field with sustained national or international acclaim.

As to the evidentiary criteria, we agree with the Director’s conclusions that the Petitioner meets the judging, scholarly articles, and high salary criteria. For judging, the record reflects that the Petitioner reviewed manuscripts for the journal *Nanomedicine: Nanotechnology, Biology, and Medicine*. For scholarly articles, the record shows that he published articles in the following journals: *Enzyme Engineering*, the *Journal of Chromatography*, and *Biochemistry and Analytical Biochemistry*. And for high salary, the record contains surveys from the American Association of Pharmaceutical Scientists indicating that the Petitioner’s base salary is high in relation to those in his field.<sup>1</sup> This

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<sup>1</sup> This conclusion on high salary is also supported by a report from the Project Management Institute in 2017 containing salary surveys for individuals in the project management field and documentation from the Career One Stop website, which is sponsored by the U.S. Department of Labor.

demonstrates that the Petitioner meets three of the ten criteria listed at 8 C.F.R. § 204.5(h)(3). Accordingly, we will evaluate the totality of the evidence in the context of the final merits determination below.<sup>2</sup>

## B. Final Merits Determination

As the Petitioner has established that he meets the requisite initial evidence, we will evaluate whether he has demonstrated, by a preponderance of the evidence, his sustained national or international acclaim and that he is one of the small percentage at the very top of the field of endeavor, and that his achievements have been recognized in the field through extensive documentation. In a final merits determination, we analyze a petitioner's accomplishments and weigh the totality of the evidence to determine if his successes are sufficient to demonstrate that he has extraordinary ability in the field of endeavor. *See* section 203(b)(1)(A)(i) of the Act; 8 C.F.R. § 204.5(h)(2)-(3); *see also Kazarian*, 596 F.3d at 1119-20.

The Petitioner received his bachelor of technology degree in chemical engineering from [redacted] University in India in 2003 and his doctorate degree in chemical engineering from the University of [redacted] in 2007. From 2008 to 2012, he was employed in positions overseeing pharmaceutical product development at [redacted] in India, and he is currently employed as a "Senior Director – Project Management" for [redacted] in New York.

On appeal, the Petitioner contends that the Director focused only on the evidence of his judging and a discussion of patents, and that he did not consider the totality of the evidence submitted in the final merits discussion. Upon review of the record in its totality, and for the reasons set forth below, we determine that the Petitioner has established that he has sustained national or international acclaim and that his achievements have been recognized in the field to show that he is "one of that small percentage who [has] risen to the very top of the field of endeavor" under 8 C.F.R. § 204.5(h)(2)-(3).<sup>3</sup>

The record contains evidence of the Petitioner's membership on the scientific advisory council of the [redacted] in India. The record contains three letters signed by the president and the general secretary of the society describing its purpose and the Petitioner's role as a member of the council. These letters indicate that the so was founded in 2012 as an international forum for pharmaceutical scientists to share knowledge and that its members include "pharmaceutical scientists from the industry, academia, and government." The June 2018 letter refers to the "stringent and rigorous screening process" for the Petitioner's admission as a member of the [redacted] scientific advisory council. One of these requirements is that the individual "should be very well recognized in the industry for his active participation in conferences and proceedings focused on the advancement of pharmaceutical dissolution sciences." The record contains evidence of several presentations the Petitioner gave at conferences focused on pharmaceutical developments in 2005 and

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<sup>2</sup> On appeal, the Petitioner references evidence pertaining to the criteria for membership at 8 C.F.R. § 204.5(h)(3)(ii), original contributions of major significance at 8 C.F.R. § 204.5(h)(3)(v), and leading or critical role at 8 C.F.R. § 204.5(h)(3)(viii), which we will consider in our final merits determination.

<sup>3</sup> *See* USCIS Policy Memorandum PM-602-0005.1, *Evaluation of Evidence Submitted with Certain Form I-140 Petitions; Revisions to the Adjudicator's Field Manual (AFM) Chapter 22.2, AFM Update AD11-14* 13 (Dec. 22, 2010), <https://www.uscis.gov/sites/default/files/USCIS/Laws/Memoranda/i-140-evidence-pm-6002-005-1.pdf>.

2007 in Ohio and Pennsylvania. The record reflects that the Petitioner has served on the [redacted] scientific advisory council since 2013. Since then, he has participated as a member of the society's round table discussion in [redacted] India in October 2013, and that he chaired its session in [redacted] India in 2016. Accordingly, the Petitioner's role on this council is a reflection of his international acclaim and recognition in the field.

Regarding the Petitioner's participation as a judge of others' work, the record reflects that he reviewed manuscripts that were published in *Nanomedicine: Nanotechnology, Biology, and Medicine*. In addition to his editorial work, he reviews a large number of abstracts as a member of the scientific advisory council for [redacted] in support of their conferences. This supports the other evidence in the record, demonstrating that the Petitioner has risen to the very top of his field.

The Petitioner indicates that he has made original contributions to the pharmaceutical industry through his work in filing patents, his role in overseeing pharmaceutical product development, and his collaboration with others in the field. The record reflects that the Petitioner was the principal inventor for an approved patent while employed at [redacted]'s Laboratories, with several others pending. [redacted] vice president of the [redacted] at [redacted] discusses the importance of this patent for the company, indicating that it forms the basis for the commercial batches of one of its key products. Similarly, [redacted], the executive vice president and chief scientific officer at [redacted], states that "[w]ithin six months of joining [redacted], [the Petitioner] was asked to take up the responsibility of leading [redacted] foray into generic injectable business by building a dedicated product development team." [redacted] then states that under the Petitioner's leadership, his team "has successfully secured [FDA] approval for nearly 15 drug products some of which are complex, high-barrier to entry and first to market generic products in the United States." [redacted] adds that not only do these products "contribute annual revenue of more than \$100M for the organization," but they also provide affordability to the American consumers, which he notes "really signifies [the Petitioner's] contribution and research in the field of pharmaceutical drug delivery."

The Petitioner also notes his collaboration with top leaders in the field. In a letter from [redacted] [redacted] the chair of pharmaceutical sciences at the University of [redacted] he states that "[the Petitioner] is one of the few industrial experts renowned for his accomplishments in the field of complex peptide characterization." [redacted] adds that "[the Petitioner] actively consults and also provides guidance to academia and industrial personnel associated with the characterization of complex peptides, proteins and biosimilar drugs." The record also contains a letter from [redacted] [redacted] the president and principal consultant for [redacted] LLC, who previously worked for the FDA reviewing "industry submissions for new biologics [biological drugs]." She states that in her subsequent role as a consultant, she has collaborated with the Petitioner in the development of biosimilars, which she indicates are "a class of biologics that are similar to an already approved, marketed product." She states that biosimilars "are usually produced in a living system, such as a microorganism or animal cell," which brings additional challenges to the manufacturing process and requires specialized expertise in "molecular and cell biology, microbiology, protein biochemistry, immunology, sterile injectable manufacturing processes, and their formulation in addition to FDA regulatory requirements [that] are needed for decision making . . . ." She discusses the role that the Petitioner has played in developing biosimilars for two specific products in particular, adding that "he

has the specialized expertise to bring these products to patients in the [United States]” and that his leadership skills “have allowed [redacted]. . . the ability to fill their pipeline with promising biosimilars.” She notes that she has collaborated with many companies and their staff in developing these products, adding that “[redacted] is fortunate to have [the Petitioner] leading their program.” This further demonstrates that the Petitioner’s original contributions are an indication that he has risen to the very top of his field and that his achievements have been recognized in the field.

With respect to the Petitioner’s scholarly articles, he notes that these have appeared in highly regarded journals in the fields of biochemical and biological science. The record reflects that his scholarly articles were published in *Enzyme Engineering*, the *Journal of Chromatography*, and *Biochemistry and Analytical Biochemistry*. In a letter from [redacted], the president and chief scientific officer at [redacted] LLC, he states that “[the Petitioner] is one of the leading experts in [redacted] process development and complex product characterization and has a couple of articles in this field that are currently under different stages of review.” When viewed together with the documentation in the record showing that the Petitioner has risen to the very top of his field, this evidence that he continues to author scholarly articles is an indication of his recognition in the field.

The Petitioner also emphasizes that he has performed leading or critical roles in product development at [redacted] Laboratories and [redacted]. The letters in the record discuss the details of the Petitioner’s work in expanding each company’s research and development (R&D) laboratories and in facilitating the submission of an Abbreviated New Drug Application (ANDA) for newly developed generic products to the FDA. The record reflects that the Petitioner has brought significant revenue to these companies in successfully leading their product development teams. In a letter from [redacted] chief executive officer of [redacted] who formerly worked for [redacted] Laboratories, he states that the Petitioner’s most significant accomplishment at [redacted] Laboratories involved setting up the “R&D facility for the Center of Excellence – Peptide and Polymer product Development.” He states, “[the Petitioner] designed the entire R&D facility and ensured that it was equipped [with] state of the art instruments needed for the development of these extremely complex biopharmaceutical drug products.” At [redacted] the company’s managing director, [redacted] indicates in his letter that “[the Petitioner] is part of a rarified group of scientists who possess the wide array of expertise on different aspects of formulation development, device development, biosimilar development, operations, quality management and also advanced analytical characterization.” He adds, “[i]n a period of close to 5 years, [the Petitioner] has established the entire R&D and manufacturing facility, has built a team of more than 100 scientists and filed close to 50 Abbreviated New Drug Applications with FDA and secured approval for close to 15 such products.” The Petitioner’s leadership within these companies is an indication that he has risen to the very top of the field. 8 C.F.R. § 204.5(h)(2).

Finally, for high salary, including his bonuses, the documentation in the record indicates that the Petitioner’s salary is high in relation to those in his field. This is another way in which the field recognizes his achievements. For the reasons discussed above, and in the totality of the evidence, the Petitioner has established that he has sustained national or international acclaim and that his achievements have been recognized in the field to show that he is “one of that small percentage who [has] risen to the very top of the field of endeavor” under 8 C.F.R. § 204.5(h)(2)-(3).<sup>4</sup>

<sup>4</sup> USCIS Policy Memorandum PM-602-0005.1, *supra*, at 13.

### III. CONCLUSION

The Petitioner has shown that he meets at least three of the evidentiary criteria listed at 8 C.F.R. § 204.5(h)(3)(i)-(x). He has also demonstrated sustained national and international acclaim and that his achievements have been recognized through extensive documentation. He therefore qualifies for classification as an individual of extraordinary ability.

In visa petition proceedings, it is the petitioner's burden to establish eligibility for the immigration benefit sought. Section 291 of the Act, 8 U.S.C. § 1361; *Matter of Skirball Cultural Ctr.*, 25 I&N Dec. 799, 806 (AAO 2012). Here, that burden has been met.

**ORDER:** The appeal is sustained.

Cite as *Matter of S-S-*, ID# 2591391 (AAO June 4, 2019)