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U.S. Citizenship and Immigration Services

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PUBLIC COPY

[redacted]

FILE: [redacted] Office: NEBRASKA SERVICE CENTER Date: SEP 16 2005

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IN RE: Petitioner:
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, Nebraska Service Center, and is now before the Administrative Appeals Office (AAO) 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 and business. The director determined that the petitioner had not established the sustained national or international acclaim requisite to classification as an alien of extraordinary ability.

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

> (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 into the United States will substantially benefit prospectively the United States.

Specific supporting evidence must accompany the petition to document the "sustained national or international acclaim" that the statute requires. 8 C.F.R. § 204.5(h)(3). An alien can establish sustained national or international acclaim through evidence of a "one-time achievement (that is, a major, international recognized award)." *Id.* Absent such an award, an alien can establish the necessary sustained acclaim by meeting at least three of ten other regulatory criteria. *Id.* However, the weight given to evidence submitted to fulfill the criteria at 8 C.F.R. § 204.5(h)(3), or under 8 C.F.R. § 204.5(h)(4), must depend on the extent to which such evidence demonstrates, reflects, or is consistent with sustained national or international acclaim at the very top of the alien's field of endeavor. A lower evidentiary standard would not be consistent with the regulatory definition of "extraordinary ability" as "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).

In this case, the petitioner seeks classification as an alien with extraordinary ability in the sciences and business as a biomedical engineer and executive for businesses that sell and manufacture medical equipment. The petitioner initially submitted supporting documents including six support letters; product information for medical devices sold by his companies; copies of articles concerning clinical studies using the technique and technology of one of these devices, the NeuroMove; two magazine articles that discusses NeuroMove and another device sold by the petitioner's companies, the AutoMove; six testimonials from doctors, patients and their family regarding the AutoMove; six letters from the Food and Drug Administration (FDA) approving the marketing of six of the petitioner's devices for prescription use; three Social Security Administration (SSA)

Administrative Law Judge (ALJ) decisions approving Medicare coverage of AutoMove; a letter from United Health Care Insurance Company certifying NeuroMove as a covered benefit; and documents concerning the registration, incorporation, insurance and sales tax licenses of three of the petitioner's companies.

In response to the director's Request for Evidence (RFE), the petitioner submitted additional materials including copies of federal income tax returns for two of his companies; documents concerning the merger and development of two of the petitioner's companies; and patent and trademark applications for NeuroMove. The latter two sets of documents were labeled as Exhibits 1 through 9 of the petitioner's RFE response. We cannot consider this evidence because it arose after the petition was filed. The petitioner must establish eligibility at the time of filing; a petition cannot be approved at a future date after the petitioner becomes eligible under a new set of facts. *See* 8 C.F.R. § 103.2(b)(12), *Matter of Katigbak*, 14 I&N Dec. 45, 49 (Comm. 1971).

On appeal, counsel submits a three-page brief and one additional support letter. Counsel's claims and the additional letter do not overcome the deficiencies of the petition and the appeal will be dismissed. We address present and former counsel's contentions and the evidence submitted in the following discussion of the regulatory criteria relevant to the petitioner's case.

> *(iii) 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.*

Prior counsel claimed the petitioner met this criterion by virtue of published clinical studies applying the technology used by the petitioner's NeuroMove device. The record contains copies of six articles and one abstract published in medical journals between 1987 and 2000. The articles and abstract discuss the efficacy of electromyogram (EMG)–triggered neuromuscular stimulation in the rehabilitative treatment of stroke victims. While the record indicates that NeuroMove works through EMG-triggered stimulation, none of the submitted articles identify NeuroMove as the device used in the clinical studies. One article, "Two Coupled Motor Recovery Protocols are Better than One," states that the device used was "an Automove (AM 800) EMG Facilitation Stimulator microprocessor." Although the record indicates that the petitioner's companies manufacture and market the AM 800, the article does not identify the petitioner or his companies. The article only mentions the AM 800 and does not discuss the device in any detail. Accordingly, none of the published clinical studies are about the petitioner's work.

The record contains an article entitled "Stimulation Device Approved for Stroke Therapy" that was published in the January 1998 edition of *Be Stroke Smart*, a publication of the National Stroke Association. The article reports that the FDA approval of AutoMove 800 for stroke therapy. The article discusses the device, the results of two clinical studies using the AM 800, and quotes the petitioner as the "spokesman for Dan Med, makers of the device." Although this article is about the petitioner's work, the record contains no evidence that *Be Stroke Smart* is a professional, major trade publication or other major media. In addition, the article was published five years before this petition was filed and does not by itself demonstrate sustained acclaim.

The petitioner also submitted an excerpt from one article that quotes the petitioner and discusses his NeuroMove device. The article is entitled "Neurotech Vendors Push New Stroke Treatment Devices" and was published in the May 2002 edition of *Neurotech Business Report*. The article reports that the petitioner's company, "Stroke Recovery Systems Inc., the Denver, CO firm that markets the AutoMove 800 system for stroke rehabilitation, recently received FDA approval for a new stroke rehabilitation product, the NeuroMove 900." The article refers

to the petitioner and discusses the special features and success rate of medical insurance reimbursement for the two devices. The petitioner's company and products are just one of several neurotech businesses discussed in the submitted excerpt and the article is not primarily about the petitioner's work. In addition, the record contains no evidence that *Neurotech Business Report* is a professional or major trade publication. Accordingly, the petitioner does not meet this criterion.

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

The petitioner submitted support letters from six experts in his field, which former counsel cited as evidence of the petitioner's eligibility under this criterion. In his decision, the director noted that "the majority of the submitted testimonials were written primarily by current and prior colleagues, admittedly at the beneficiary's request." On appeal, counsel contends that the director "appears to impugn the integrity of these renowned individuals and say that such letters cannot be used as evidence of [the petitioner's] extraordinary ability, because they are not as credible as letters from independent sources. Such rationale, however, goes beyond established law and creates a new legal standard, an approach which the courts have found to be unacceptable." We do not read the director's comments as impugning the integrity of the letters' authors or as going beyond the statute and regulation. Rather, the director's comments reflect his understanding that while testimonial letters provide relevant information about an alien's experience and accomplishments, they cannot by themselves establish the alien's eligibility under this criterion because they do not demonstrate that the alien's work is of major significance in his field beyond the limited number of individuals with whom he has worked directly. Even when written by independent experts, letters solicited by an alien in support of an immigration petition carry less weight than preexisting, independent evidence of major contributions that reflects sustained national or international acclaim. Accordingly, we review the letters as they relate to other evidence of the petitioner's contributions.

The petitioner claims to satisfy this criterion by virtue of his development of six medical devices as a biomedical engineer. The record indicates that, at the time of filing, the petitioner was the president and registered agent of Dan Med Incorporated (DMI) and Stroke Recovery Systems Incorporated (SRSI). The evidence shows that these two companies manufacture and market the AM 800, the E-Wave, NeuroMove 900, Interferential Therapy (IF) 8000, TruWave, EMS 3000, and the Elpha 2000 Conti. Stephen J. Page, Director of Research and Assistant Professor in the Department of Physical Medicine and Rehabilitation at the University of Cincinnati College of Medicine, describes the petitioner as "an important scientist and businessperson in the field of stroke motor recovery." Dr. Page credits the petitioner with the development of the Neuromove and states that published clinical studies using the Neuromove attest to its success in the rehabilitation of stroke victims. Dr. Page claims the petitioner's "device has also restored function in hundreds of stroke patients who had been discharged and/or 'written off' by the medical community" and has caused "many clinicians to rethink their views of stroke recovery." Yet, as discussed above under the third criterion, none of the submitted articles identify Neuromove or the petitioner and the record contains no corroborative evidence of the clinical studies using the Neuromove as cited by Dr. Page.

James H. Cauraugh, Associate Professor and Director of the Motor Behavior Laboratory at the University of Florida, states that he first met the petitioner in 1997 and has frequently consulted him since that time. Dr. Cauraugh explains that "[t]wo of [his] grant proposals on relearning movements after a stroke have been funded. Most importantly, the Automove (AM 800) and electromyography triggered neuromuscular stimulation have been central components of each grant. [The petitioner] has continually supported us during

device and testing challenges." Dr. Cauraugh is the lead author of an article entitled "Chronic Motor Dysfunction After Stroke[:] Recovering Wrist and Finger Extension by Electromyography-Triggered Neuromuscular Stimulation" that was published in June 2000 in *Stroke* and which states that the AM 800 was used in the clinical study. However, Dr. Cauraugh does not identify the petitioner as the engineer or developer of the AM 800.

The support letters submitted with the petition also credit the petitioner with the design and development of the Elpha 2000 Conti and a device to detect central blood loss. Yet the petitioner submitted no corroborative evidence that he is the designer or developer of these or any other medical devices. The record contains no copies of, for example, scholarly articles identifying the petitioner as the engineer of these medical devices and no patents or trademarks identifying the petitioner as the inventor of these products. With his RFE response, the petitioner submitted a United States provisional patent application and a trademark notice of publication, but we cannot consider this evidence because it arose after the petition was filed. The petitioner must establish eligibility at the time of filing; a petition cannot be approved at a future date after the petitioner becomes eligible under a new set of facts. *See* 8 C.F.R. § 103.2(b)(12), *Katigbak*, 14 I&N Dec. at 49. Hence, the record does not establish that the products manufactured or marketed by the petitioner's companies constitute the petitioner's own original scientific contributions to his field.

The record similarly fails to establish that the petitioner has made original business-related contributions of major significance to his field through his marketing of medical devices. Jennifer M. McCallum, an intellectual property attorney specializing in the biotechnology and medical device market sectors, states that the petitioner is "a truly unique biomedical engineer researcher, regulatory specialist and business man. These traits make him one of the very few market participants in the world able to successfully navigate this field; resulting in the creation, FDA approval and distribution of multiple medical devices to aid stroke recovery and spinal cord injury patients." Ms. McCallum explains that the petitioner obtained FDA approval for six of his medical devices in one year while representing himself pro se, a feat she describes as "unmatched to my knowledge." Ms. McCallum also notes that the petitioner "has successfully prosecuted over 100 claims for Medicare payment for the use of these devices." Ms. McCallum further states that "[i]t is highly unusual to have the inventor of the devices running the company based on those devices, let alone also directing those devices through the regulatory process." She describes the petitioner as "an extremely skilled entrepreneur" who has "helped the company produce revenues of over $3 million and grow to over 20 employees in merely a few years."

J. Joseph Marr, President and Chief Executive Officer of BioMed, LLC, states that the FDA approval of six devices marketed by the petitioner's companies and his successful prosecution of "over 100 claims for Medicare payment" for these devices are "the very definition of an entrepreneur and a successful business leader. He is the only person I know who has achieved this type of success." Dr. Marr further explains that the petitioner has "grown his revenues to over $3 million in just a few years and created more than 20 jobs. This is a very good record for a small business, especially since the US economy has been definitely unfavorable for the past three of those years." Dr. Marr concludes that the petitioner's "combination of a biomedical engineering degree with an entrepreneurial flair allows him to make a substantial contribution to the medical device industry, as well as the US economy."

The record only partially corroborates the statements of Ms. McCallum and Dr. Marr. The petitioner submitted evidence that the FDA approved the marketing of six devices manufactured and sold by DMI and SRSI. The record contains copies of three SSA ALJ decisions approving Medicare coverage of AutoMove, but no further evidence to corroborate the petitioner's alleged win of "over 100 claims" for Medicare coverage. The record

confirms Ms. McCallum's and Dr. Marr's statements regarding the companies' revenues. The petitioner submitted evidence that DMI was incorporated in 1996 and that SRSI was incorporated in 1998. The federal income tax returns for DMI and SRSI show combined gross sales of $3,129,624 in 2002; $2,290,476 in 2001; $1,158,454 in 2000; and $660,056 in 1999. Yet the record does not indicate that DMI and SRSI have over 20 employees, as stated by Ms. McCallum and Dr. Marr. The only other evidence concerning the number of the companies' employees is the letter of Ronald Nelson Baird, Executive Director of the Colorado Ventures Centers Incorporated, who states that the petitioner "created 10 jobs in the biotech industry in Colorado." Dr. Marr states that the petitioner's companies "employ abut [sic] twenty people."

Mr. Baird and Kevin M. Connolly, Chief Executive Officer of SRS Medical Systems Incorporated, also attest to the petitioner's successful business endeavors. While the support letters and the income tax returns of DMI and SRSI show that the petitioner has led two profitable businesses, the record does not establish that his entrepreneurial success resulted in original scientific or business-related contributions of major significance in his field. The record does not persuasively demonstrate that the petitioner is the inventor, designer or engineer of any of the medical devices manufactured or distributed by his companies. While the record indicates that the petitioner possesses an unusual combination of scientific and business skills that have contributed to his companies' success, the evidence does not demonstrate that his work has been widely recognized by business executives or industry experts as making major contributions to his field. Accordingly, the petitioner does not meet this criterion.

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

On page nine of former counsel's initial brief, he claimed the petitioner met this criterion because he "has been consulted by and his devices used by Washington University School of Medicine and The University of Cincinnati College of Medicine." The record does not support this claim. One of the submitted articles, "Techniques to Improve Function of the Arm and Hand in Chronic Hemiplegia," discusses a study conducted and funded in part by the Department of Rehabilitation Medicine at the University of Washington, but the article does not mention the petitioner or any of his companies' medical devices. Dr. Marr's resume states that he was an Associate Professor at the Washington University School of Medicine from 1970 to 1976, but his employment ended well before the petitioner began working in his present field. Dr. Page, of the University of Cincinnati College of Medicine, praises the NeuroMove and discusses the results of studies using this device for stroke motor recovery. Yet Dr. Page does not state that he or any other medical staff at the University of Cincinnati have actually used the NeuroMove in their treatment of stroke victims.

On page four of former counsel's RFE response, he equivocally states that this criterion does not apply to the petitioner's case. Nonetheless, the record contains evidence relevant to this criterion which merits brief discussion. As documented by the support letters, business materials, two magazine articles, FDA notifications and SSA ALJ decisions submitted with the petition, as well as the DMI and SRSI tax returns submitted with the RFE response, the petitioner performs a leading and critical role for DMI and SRSI. However, the record contains no evidence that these two companies have distinguished reputations. The tax returns and several support letters indicate that the petitioner's companies are successful, but the record contains no evidence that the companies' revenues or profits are significantly higher than other companies of comparable size in the medical device industry. While the two magazine articles quote the petitioner and discuss his companies' products, the articles do not feature DMI or SRSI as industry leaders or distinguished companies. Accordingly, the petitioner does not meet this criterion.

(ix) Evidence that the alien has commanded a high salary or other significantly high remuneration for services, in relation to others in the field.

On page ten of his initial brief, former counsel stated, "Although [the petitioner] may not personally have commanded a high salary or other significantly high remuneration for his services, in relation to others in the field, in satisfaction of 8 C.F.R. § 204.5(h)(3)(ix), the fact that his companies have been so successful in such a short period of time . . . , in an industry in which failure is the norm, would seem to satisfy this requirement." The language of this regulatory criterion clearly requires evidence of the alien's own salary or remuneration. However, we have considered the revenues of the petitioner's companies as comparable evidence of his eligibility under the tenth criterion as discussed below.

On page four of former counsel's RFE response, he states that this criterion does not apply to the petitioner's case. Regardless of former counsel's equivocal statements, the record does not show that the petitioner's income is significantly higher than other similarly employed individuals in his field or comparable to such individuals at the very top of his field. Accordingly, he does not meet this criterion.

(x) Evidence of commercial successes in the performing arts, as shown by box office receipts or record, cassette, compact disk, or video sales.

The petitioner did not claim to meet this criterion, but the record indicates that the petitioner's companies have been profitable and we consider the relevant documents as comparable evidence for this category pursuant to 8 C.F.R. § 204.5(h)(4).

Ms. McCallum states that the petitioner's skills have helped his companies "produce revenues of over $3 million and grow to over 20 employees in merely a few years. This is an extraordinary record for any small business, let alone one in the medical device industry. [The petitioner] is likely one of very few in this industry capable of this track record." Dr. Marr explains that "[a]lthough he has been in this country only since 1996, [the petitioner] has invented at least six medical devices and had them approved for payment by Medicare. This is a necessary first step toward commercial success. . . . [The petitioner] has grown his revenues to over $3 million in just a few years . . . . This is a very good record for a small business, especially since the US economy has been definitely unfavorable for the past three of those years. [The petitioner] is very unusual in that he has been able to be cash-flow positive in such a short time." Mr. Connolly also praises the petitioner for building "a successful manufacturing and distribution company in physical therapy and rehabilitative medicine, an underserved area [sic], and done this during a difficult economy." Combined with the evidence mentioned above under the eighth criterion, these letters indicate that the economic viability of DMI and SRSI is directly attributable to the petitioner.

However, the record is devoid of any evidence that DMI and SRSI have been significantly more profitable or have generated substantially more revenues than other small businesses in the petitioner's field in a manner reflective of the requisite sustained acclaim. The federal income tax returns for DMI and SRSI show combined gross sales of $3,129,624 in 2002; $2,290,476 in 2001; $1,158,454 in 2000; and $660,056 in 1999 and combined total income of $1,020,762 in 2002; $910,804 in 2001; $724,237 in 2000; and $374,074 in 1999. Yet the record contains no evidence to corroborate the assessment of Ms. McCallum and Dr. Marr that these revenues and profits were "extraordinary" or "very good" for comparable small businesses in the medical device industry during this time period. Accordingly, the petitioner does not meet this criterion.

In his decision, the director explained that the importance of the petitioner's work was not at issue in this petition. Rather, he stated, "[t]he issue is limited to whether, through evidence of sustained national or international acclaim, the petitioner is recognized as one of that small percentage who have risen to the very top of his fields." On appeal, counsel contends that "such a standard falls well beyond the confines of established law" and cites an unpublished AAO decision for the proposition that "the standard is 'sustained national acclaim' and not being at the 'top of their field.'" Counsel's contention is misguided for two reasons. First, designated and published decisions of the AAO are binding precedent on all Service employees in the administration of the Act pursuant to 8 C.F.R. § 103.4(c), yet unpublished decisions have no such precedential value. Second, the director's statement does not indicate that he evaluated the record under a standard outside of the statute and regulation. Instead, his comment reflects his understanding that section 203(b)(1)(A)(i) of the Act, 8 U.S.C. § 1153(b)(1)(A)(i), states that an alien's extraordinary ability must be demonstrated by sustained national or international acclaim and that the regulation at 8 C.F.R. § 204.5(h)(2) defines "extraordinary ability" as "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."

We have reviewed the record and evaluated the petitioner's eligibility under four of the regulatory criteria at 8 C.F.R. § 204.5(h)(3) and under the comparable evidence provision of 8 C.F.R. § 204.5(h)(4). The evidence submitted does not demonstrate that the petitioner had achieved sustained national or international acclaim in his fields at the time of filing. On appeal, the petitioner submits a letter from Paul S. Ruwalt, Test Director at the Transportation Security Laboratory of the Transportation Security Administration. We cannot consider this letter because Mr. Ruwalt discusses events which the record indicates occurred after the petition was filed. The petitioner must establish eligibility at the time of filing. *See* 8 C.F.R. § 103.2(b)(12), *Katigbak*, 14 I&N Dec. at 49. Mr. Ruwalt's letter is dated January 21, 2005 and states, "I have signed an NDA [Non-Disclosure Agreement] with [the petitioner], as a consultant, to assist my team in developing test protocols and a concept of operations (CONOPs) for such biometric technologies as Facial, Voice and Hand Geometry recognition biometric systems." Mr. Ruwalt does indicate when he signed the NDA with the petitioner, but counsel states on appeal that "[b]ecause this NDA represents a recent development, this information was not available at the time of the initial submission." Hence, the petitioner's work with Mr. Ruwalt arose after the petition was filed and cannot be considered. *Id.*

An immigrant visa will be granted to an alien under section 203(b)(1)(A) of the Act, 8 U.S.C. § 1153(b)(1)(A), only if the alien can establish extraordinary ability through extensive documentation of sustained national or international acclaim demonstrating that the alien has risen to the very top of his or her field. The evidence in this case indicates that the petitioner leads two successful medical device companies. However, the record does not establish that the petitioner had achieved sustained national or international acclaim as a biomedical engineer or business executive at the time of filing. He is thus ineligible for classification as an alien with extraordinary ability pursuant to section 203(b)(1)(A) of the Act, 8 U.S.C. § 1153(b)(1)(A).

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.