

Canadian International Trade Tribunal Tribunal canadien du commerce extérieur

CANADIAN International Trade Tribunal

Appeals

DECISION AND REASONS

Appeal No. AP-2018-054

Osiris Inc.

v.

President of the Canada Border Services Agency

> Decision issued Friday, February 26, 2021

> Reasons issued Tuesday, March 16, 2021

Canadä

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IN THE MATTER OF an appeal heard on October 30, 2020, pursuant to section 67 of the *Customs Act*, R.S.C., 1985, c. 1 (2nd Supp.);

AND IN THE MATTER OF a decision of the President of the Canada Border Services Agency, dated October 2, 2018, with respect to a request for re-determination pursuant to subsection 60(4) of the *Customs Act*.

BETWEEN

OSIRIS INC.

AND

THE PRESIDENT OF THE CANADA BORDER SERVICES AGENCY

Respondent

Appellant

DECISION

The appeal is dismissed.

Susan D. Beaubien Susan D. Beaubien Presiding Member

The statement of reasons will be issued at a later date.

Tribunal Panel: Support Staff:

PARTICIPANTS:

Appellant

Osiris Inc.

Respondent

President of the Canada Border Services Agency

WITNESSES:

Samir Kulkarni CEO of Showcase Kate Berry Registered Occupational Therapist

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By videoconference October 30, 2020

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STATEMENT OF REASONS

OVERVIEW

[1] This appeal arises from the importation by Osiris Inc. (Osiris) of DreamAway Calming Weighted Blankets (DreamAway Blankets). These goods were classified by the President of the Canada Border Services Agency (CBSA) for the purposes of the *Customs Tariff*,¹ as articles of bedding within the scope of tariff heading no. 9404.²

[2] Osiris did not contest this classification but took the position that the goods qualify for duty-free treatment pursuant to tariff item no. 9979.00.00 as "[g]oods specifically designed to assist persons with disabilities in alleviating the effects of those disabilities, and articles and materials for use in such goods." The CBSA disagreed and denied duty relief.

[3] Osiris now appeals to the Tribunal.

[4] Just prior to the hearing of its appeal, Osiris submitted that the DreamAway Blankets should instead be classified in heading no. 39.26 as articles of plastics and, only in the alternative, under tariff item no. 9404.90.10. In either case, Osiris takes the position that the DreamAway Blanket should be afforded duty-free treatment pursuant to tariff item no. 9979.00.00.

FACTUAL BACKGROUND

[5] On December 27, 2017, Osiris sought an advance ruling from the CBSA concerning whether the DreamAway Blanket qualified for duty-free treatment.³

[6] The CBSA concluded that the goods did not meet the requirements of tariff item no. 9979.00.00. Osiris disputed this conclusion and appealed to the CBSA's Recourse Directorate on April 27, 2018, pursuant to section 60(2) of the *Customs Act.*⁴

CBSA's Decision

[7] The DreamAway Blanket was described by the CBSA as being made of 100 percent cotton and filled with pellets of plastic material. It weighs 10 pounds and is 74 inches long and 39 inches wide. The CBSA noted that the product description states that "weighted blankets are therapeutic and are helpful for sleeping issues to individuals such as Autism, Sleep Apnea, Restless leg syndrome, Narcolepsy, Jet Lag, Shift-work, Night Terrors, Work Related Stress, and Anxiety. ... mimic deep pressure touch stimulation and thus have a calming and soothing effect ... "⁵

[8] The CBSA noted Osiris's representations that the DreamAway Blankets "can be purchased without a medical prescription and that, they assist [some] people suffering from disabilities such as ADD/ADHD Spectrum Disorder, Asperger's and Autism Spectrum Disorder".⁶ In support of these contentions, Osiris filed product advertising and marketing materials; published articles discussing

¹ S.C. 1997, c. 36.

² More particularly, the goods were classified under tariff item no. 9404. 90.10.

³ Exhibit AP-2018-054-27 at 46-49.

⁴ Exhibit AP-2018-054-11 at 22.

⁵ Exhibit AP-2018-054-01 at 9.

⁶ *Ibid.*

the properties, uses and effects of weighted blankets; excerpts from CBSA Memorandum D10-15-24; and copies of Tribunal decisions.⁷

[9] Having reviewed this material, the CBSA concluded that the product advertising did not provide sufficient information relevant for the purposes of tariff item no. 9979.00.00. No information was provided concerning how the needs of persons with disabilities "was consciously taken into account and deliberately factored into the research, design and development of the specific good in issue". Nor did the documents submitted by Osiris persuade the CBSA that the DreamAway Blanket was "specifically aimed" at the alleviation of disabilities or that the intended result had been achieved.⁸

[10] The CBSA noted that various weighted blankets are available on the market. The scientific article submitted by Osiris was supported by a financial grant of a particular manufacturer and was limited to a discussion of a particular type of weighted blanket, namely a "chain-weighted" type of blanket.

[11] Documents emanating from third parties were considered inadequate to demonstrate that the DreamAway Blankets were "specifically designed to alleviate the effects of a disability."

[12] Accordingly, the CBSA concluded⁹ that the DreamAway Blanket does not qualify for the benefit of the duty-free treatment provided by tariff item no. 9979.00.00 and confirmed its advance ruling.¹⁰

[13] The CBSA issued its decision on October 2, 2018.¹¹ Osiris filed this appeal with the Tribunal on December 14, 2018.¹²

Procedural Matters

[14] The wording of the tariff provision at issue changed while this appeal was pending before the Tribunal. At the time the goods were imported, tariff item no. 9979.00.00 read as follows:

- 9979.00.00 -Goods specifically designed to 9979.00.00 assist persons with disabilities in alleviating the effects of those disabilities, and articles and materials for use in such goods.
 - O -Marchandises conçues spécifiquement pour assister les personnes handicapées en allégeant les effets de leurs handicaps, et articles et matières devant servir dans ces marchandises.

⁷ *Ibid.* at 10.

⁸ Ibid.

⁹ Exhibit AP-2018-054-27 at 7-8, 3-6.

¹⁰ Exhibit AP-2018-054-01 at 10; Exhibit AP-2018-054-27 at 3-6.

¹¹ Exhibit AP-2018-054-01 at 9.

¹² *Ibid.*

[15] Effective January 1, 2019, the wording of tariff item no. 9979.00.00 was amended to read as follows:

9979.00.00- -Goods specifically designed
to alleviate the specific effects of a disability,
and articles and materials for use in such
goods9979.00.00- -Marchandises conçues
spécifiquement pour alléger les effets
spécifiquement d'une invalidité, et articles et
matières devant servir dans ces marchandises

[16] The interpretation of the new wording of tariff item no. 9979.00.00 was also at issue in an unrelated appeal (AP-2018-052) that was copending before the Tribunal. The Tribunal invited the parties to this appeal to comment upon whether they wished to adopt a similar procedure to the one used in AP-2018-052 concerning the making of submissions with respect to the amended wording of tariff item no. 9979.00.00. The Tribunal further advised that the parties could request that this appeal be held in abeyance.¹³

[17] At the request of the parties, the Tribunal ordered that this appeal be held in abeyance pending a decision in AP-2018-52.¹⁴ Following the discontinuance of AP-2018-052, this appeal resumed and the parties were again provided with the opportunity to make submissions concerning the amendments to tariff item no. 9979.00.00.¹⁵

[18] The date for the hearing of the appeal was again adjourned, at the request of the appellant, due to a scheduling conflict.¹⁶ Following consultation with the parties, the hearing was rescheduled to be held as a videoconference hearing, due to the restrictions imposed by the COVID-19 pandemic.¹⁷

Additional Evidence on Appeal

[19] In support of its appeal, Osiris filed the following:

- (a) a copy of the decision under appeal; 18
- (b) a product information sheet for the goods at issue;¹⁹
- (c) an article published in 2015 in the *Journal of Sleep Medicine & Disorders* entitled "Positive Effects of a Weighted Blanket on Insomnia;"²⁰
- (d) a printout of a 2016 blog from harkla.co entitled "What is a Weighted Blanket and What are the Benefits of Them?"²¹,²¹

¹³ Exhibit AP-2018-054-05.

¹⁴ Exhibit AP-2018-054-09.

¹⁵ Exhibit AP-2018-054-10; Exhibit AP-2018-054-11; Exhibit AP-2018-054-12; Exhibit AP-2018-054-13.

¹⁶ Exhibit AP-2018-054-15; Exhibit AP-2018-054-16.

¹⁷ Exhibit AP-2018-054-28.

¹⁸ Exhibit AP-2018-054-01 at 9-12.

¹⁹ Exhibit AP-2018-054-27 at 9-12.

²⁰ *Ibid.* at 13-19; Exhibit AP-2018-054-27 at 240-246.

²¹ Exhibit AP-2018-054-27 at 20-25.

- (e) an article entitled "The Seductive Confinement of a Weighted Blanket in an Anxious Time" published by *The New Yorker* on February 26, 2018;²²
- (f) documents with respect to the request for an advance ruling as to whether the goods qualify for duty-free treatment;²³
- (g) documents with respect to the request for reconsideration of the advance ruling filed with the Recourse Directorate;²⁴
- (h) correspondence with the Chinese manufacturer of the DreamAway Blanket with respect to product testing and certifications;²⁵
- (i) documents concerning product testing and certifications;²⁶
- (j) documents characterized as "Importer quote sheets";²⁷
- (k) documents described as "manufacturer's marketing material";²⁸
- (l) printouts from the importer's website;²⁹
- (m) publications from the Quebec government entitled "L'utilisation des couvertures, des vestes et autres objets lestés auprès des enfants: information, mise en garde et précautions d'usage" and "Weighted Blankets and Vests: Safety, Efficacy and Issues Related to Their Use in Different Intervention Settings;"³⁰
- (n) copies of a slideshow entitled "Exploring the Safety and Effectiveness of the Use of Weighted Blankets with Adult Populations" presented at the 2007 Annual Conference of the American Occupational Therapy Association;³¹
- (o) an article published in 2018 by Platinum Health and entitled 'The Benefits of Weighted Blankets Against Stress, Anxiety, and Insomnia;"³²
- (p) an excerpt apparently taken from the website of The National Autistic Society of the United Kingdom from 2018 entitled "Weighted Items and Autism;"³³
- (q) an abstract taken online from a journal article entitled "Occupational Therapy in Mental Health" published in 2008, entitled "Exploring the Safety and Therapeutic Effects of Deep Pressure Stimulation Using a Weighted Blanket;"³⁴

²⁷ *Ibid.* at 101-106.

²⁹ *Ibid.* at 131-134.

³¹ *Ibid.* at 147-228.

²² *Ibid.* at 26-31.

²³ *Ibid.* at 42-49.

²⁴ *Ibid.* at 32-41.

²⁵ *Ibid.* at 50.

²⁶ *Ibid.* at 51-100.

²⁸ *Ibid.* at 107-130.

³⁰ *Ibid.* at 135-146.

³² *Ibid.* at 229-232.

³³ *Ibid.* at 233-234.

- (r) an online article or blog of unknown source purportedly authored in 2019 by "Purple Staff" entitled "What is a Weighted Blanket or Heavy Comforter and What are the Benefits?;"³⁵
- (s) an online article or blog from an unidentified website purportedly authored in 2018 by Suzy Cohen entitled "Ask the Pharmacist: 5 reasons you'll want a weighted blanket;"³⁶
- (t) an online article or blog from an unidentified website purportedly authored in 2019 by Eleesha Lockett MS and "medically reviewed" by Stacy Simpson D.O. entitled "Weighted Blankets: Do They Work?;"³⁷and
- (u) a copy of CBSA Memorandum D10-15-24 with respect to the interpretation and application of tariff item no. 9979.00.00.³⁸

[20] Osiris also filed the expert report,³⁹ undertaking⁴⁰ and *curriculum vitae*⁴¹ of Kate Berry. Ms. Berry is an occupational therapist who is registered with the province of Ontario. She holds a Bachelor of Science degree in Human Kinetics from the University of Ottawa and a Master of Science degree in Occupational Therapy from McMaster University.

[21] Osiris also gave notice of its intention to call Samir Kulkarni as a fact witness. Mr. Kulkarni is the Chief Executive Officer and owner of Osiris, which does business using the trade name Showcase.⁴²

[22] In addition, Osiris also submitted a sample of the DreamAway Blanket as a physical exhibit.

[23] In its responding materials, the CBSA submitted copies of Osiris's request for an advance ruling,⁴³ the advance ruling⁴⁴ and the decision under appeal.⁴⁵ In supplementary written materials,⁴⁶ the CBSA filed copies of dictionary definitions for "bedding" and "bedclothes."⁴⁷

[24] Both parties also submitted written arguments, together with copies of relevant statutory authorities and jurisprudence relied upon.

Oral Hearing

[25] The appeal was heard on October 30, 2020, using the Cisco Webex platform. Both parties were represented throughout.

- ⁴³ Exhibit AP-2018-054-11 at 22-29.
- ⁴⁴ *Ibid.* at 18-20.
- ⁴⁵ *Ibid.* at 31-34.
- ⁴⁶ Exhibit AP-2018-054-44.
- ⁴⁷ *Ibid.* at 52-67.

³⁴ *Ibid.* at 235-239.

³⁵ *Ibid.* at 247-258.

³⁶ *Ibid.* at 259-260.

³⁷ *Ibid.* at 261-266.

³⁸ *Ibid.* at 267-269.

³⁹ Exhibit AP-2018-054-18.

⁴⁰ Exhibit AP-2018-054-19.

⁴¹ Exhibit AP-2018-054-27A.

⁴² *Transcript of Public Hearing* at 4, 6.

<u>Samir Kulkarni</u>

[26] Mr. Kulkarni was called as a witness by Osiris. He testified that Osiris is a product developer, importer, marketer and retailer of health items, among other products. Doing business under the tradename Showcase, Osiris operates 117 stores within Canada and the United States.⁴⁸

[27] The DreamAway Blanket is manufactured in China and imported into Canada by Osiris. Mr. Kulkarni described the goods in issue as a "device to help with deep pressure stimulation..." with the idea of helping people suffering from medical ailments, "... specifically autism, ADHD, in some cases insomnia, restless leg syndrome and others"

[28] The product packaging of the DreamAway Blanket contains the following statement:

For people who suffer from anxiety, insomnia, or autism, weighted blankets may provide a safe way to complement existing therapies. By providing deep pressure touch, weighted blankets can promote relaxation and help you feel more grounded.⁵⁰

[29] Mr. Kulkarni characterized the product packaging of the DreamAway Blanket as a "carrying bag" which he asserted was inherent to the utility of the DreamAway Blanket as a therapy device because it enables the blanket to be brought to a person in need or facilitates its transport to therapy sessions.⁵¹

[30] Mr. Kulkarni stated that he was personally involved with working on the design of the DreamAway Blanket, together with Osiris's offshore supplier and members of Osiris's product development team. In furtherance of Osiris's design objectives for the product, Osiris's Director and Senior Buyer travelled to China on several occasions⁵² to visit the manufacturing facility.⁵³

[31] On cross-examination, Mr. Kulkarni stated that the design process with which he had been personally involved had generated correspondence, drawings, photographs, draft specifications and factory drawings. He did not know why copies of this material had not been filed in support of the appeal but ascribed this to "legal strategy". He contended that the outcome of this design process was reflected by the content of the product quote sheets.⁵⁴

[32] According to Mr. Kulkarni, the dimensions of the DreamAway Blanket are critical as there must be an equal and consistent amount of weight distributed across the body. As such, the dimensions of the product are tailored to the size and weight of the user, unlike conventional bed linens. The stitching is also a critical aspect of the product as it narrow and strong in order to enable even distribution of the blanket's weight which derives from high density polyethylene pellets. The use of inorganic material such as polyethylene is essential, according to Mr. Kulkarni, because the

⁴⁸ *Transcript of Public Hearing* at 4, 6.

⁴⁹ *Ibid.* at 5.

⁵⁰ *Ibid.* at 19.

⁵¹ *Ibid.* at 19-20.

⁵² Approximately four or five times. *Transcript of Public Hearing* at 28-29.

⁵³ *Transcript of Public Hearing* at 5-6.

⁵⁴ *Ibid.* at 27-28.

use of organic material as a filler is neither safe nor sanitary. The product also features blanket ties which serve to attach the blanket to its surrounding washable cover.⁵⁵

[33] Osiris maintains contact information concerning customers of the DreamAway Blanket, which were stated by Mr. Kulkarni to encompass hundreds of customers including governments, healthcare agencies, youth services, autism services providers and school boards.⁵⁶ However, no documentary evidence to this effect was submitted.

[34] Mr. Kulkarni stated that the DreamAway Blanket is not a bedding product, but a "very specialized health item" that would not be sold in retail outlets that sell bedding.⁵⁷

[35] During his testimony, Mr. Kulkarni confirmed that certain documents filed by Osiris in support of its appeal had been obtained from Osiris's supplier, i.e. Hangzhou Kuangs Textile Co., Ltd. (Kuangs), in China.⁵⁸ The product testing and certification materials were provided by Kuangs, upon the request of Osiris's counsel.⁵⁹ On cross-examination, Mr. Kulkarni appeared to be generally unfamiliar with the specifics of the individual tests that underpinned the product certifications or whether the certifications had been obtained before or after the design work undertaken for the DreamAway Blanket.⁶⁰

[36] On direct examination from Osiris's counsel, Mr. Kulkarni read certain excerpts from documents filed by Osiris into the record, including portions of the manufacturer's marketing materials, product testing results and certifications, and Osiris's quote sheet which describes product specifications.⁶¹

[37] Osiris is a supporter of Autism Canada.⁶² In view of this, Mr. Kulkarni stated that Osiris had developed the DreamAway Blanket for use by those suffering from autism. A portion of the proceeds from the sale of each DreamAway Blanket is donated towards the cause of Autism Canada.⁶³

[38] On cross-examination, Mr. Kulkarni conceded that Osiris had not sought a medical device licence from Health Canada for the DreamAway Blanket, notwithstanding that Osiris considers the item to be a therapeutic product. According to Mr. Kulkarni, such a licence was not required, having regard to customer needs, as communicated to Osiris by its customers.⁶⁴

- ⁵⁶ *Ibid.* at 7.
- ⁵⁷ *Ibid.* at 22-23.
- ⁵⁸ *Ibid.* at 8, 15.
- ⁵⁹ *Ibid.* at 29-31.
- ⁶⁰ *Ibid.* at 31-37.
- ⁶¹ *Ibid.* at 8-17.
- ⁶² *Ibid.* at 18.
- ⁶³ *Ibid.*
- ⁶⁴ *Ibid.* at 24-27.

⁵⁵ *Ibid.* at 20-22.

Kate Berry

[39] Ms. Berry has been an occupational therapist for over fifteen years. She also works as a rehabilitation case manager and teaches part-time at Algonquin College in the Occupational Therapy Assistant/Physiotherapy Assistant Diploma Program.⁶⁵

[40] Occupational therapists are regulated health professionals. The purpose of occupational therapy is to enable function, independence and quality of life, with a view to improving functional performance in meaningful activity or occupation. This work includes aspects of self-care, emotional regulation and productivity in various aspects of a client's life.⁶⁶

[41] In the course of her practice, Ms. Berry works with individuals having physical, sensory or cognitive disabilities. Many of her clients have been injured in motor vehicle accidents and deal with mental health issues, anxiety, depression, post-traumatic stress disorder (PTSD) and chronic pain. She has also worked with children having fine motor or sensory issues, including autism.⁶⁷

[42] Ms. Berry has experience performing comprehensive in-home assessments, hospital discharge planning and interventions which may include the development and implementation of return to work and resumption of daily activities programs. Her experience further comprises the treatment of individuals having a range of physical, cognitive and psychosocial/behavioural impairments at various stages of life, i.e. from pediatric to geriatric care.⁶⁸

[43] The CBSA did not object to the admission of Ms. Berry as an expert witness. Having considered the factors underpinning the admissibility of expert evidence,⁶⁹ the Tribunal admitted Ms. Berry as an expert witness having expertise as an occupational therapist with some experience in the treatment of obsessive-compulsive disorder, attention deficit hyperactivity disorder (ADHD) and other similar conditions.⁷⁰ Her written report was deemed to be incorporated as testimony before the Tribunal.⁷¹

[44] Ms. Berry testified that occupational therapy is client-centred with techniques and therapy tailored to the needs and life circumstances of the individual who is being treated.⁷² She also provided an overview of the nature of, and symptoms associated with, a range of conditions including sensory integrative disorders, autism spectrum disorder, ADHD, and sleep disorders. Over the course of her career, Ms. Berry has treated individuals with all of these conditions.⁷³

[45] Ms. Berry's written report notes that the scientific evidence establishing the use of weighted blankets is limited:

While there is not a vast body of experience regarding the therapeutic nature of weighted blankets, a brief review of recent Occupational Therapy journals finds much of the literature is related to use of weighted blankets, vests, lap pads etc. with individuals with Autism

⁶⁵ Exhibit AP-2018-054-27A; Exhibit AP-2018-054-18; *Transcript of Public Hearing* at 40-41.

⁶⁶ *Transcript of Public Hearing* at 41.

⁶⁷ *Ibid.* at 41-42.

⁶⁸ Exhibit AP-2018-054-18 at 2; *Transcript of Public Hearing* at 41-42.

⁶⁹ *R. v. Mohan*, [1994] 2 S.C.R. 9; *White Burgess Langille Inman v. Abbott and Haliburton Co.*, 2015 SCC 23.

⁷⁰ *Transcript of Public Hearing* at 59.

⁷¹ *Ibid.* at 58.

⁷² *Ibid.* at 43-44.

⁷³ Exhibit AP-2018-054-18 at 3; *Transcript of Public Hearing* at 44-47, 49-53.

Spectrum Disorder and Sensory Processing Disorders or Sensory Integrative Disorders. Other populations include those with Attention Deficit Hyperactivity Disorder, anxiety, developmental disorders and sleep disorder. Application of sensory processing strategies for individuals with traumatic/acquired brain injury is in its infancy but appears to hold promise. A review of the literature found that goals of weighted blanket use via the provision of deep pressure and increased proprioceptive input tended to include improving sleep hygiene, reducing anxiety, improving focus etc.⁷⁴

[46] The underlying theory is that the weighted blanket provides proprioceptive input to slow down the central nervous system. The sustained pressure applied to the body by the weighted blanket can provide a calming, relaxing sensory input which replaces, distracts or interrupts the body's pain circuitry, thus providing pain relief. In individuals with sensory modulation issues, the deep pressure provided by a weighted blanket may override signals misinterpreted by the brain as being dangerous or threatening and thus provide a calming effect.⁷⁵

[47] Ms. Berry also discussed a theory that pressure applied by a weighted blanket can increase the availability of serotonin within the body. Serotonin is a precursor to melatonin, which plays a role in the regulation of the body's sleep/wake system. Higher levels of melatonin are believed to lead to better quality of sleep.⁷⁶

[48] Although there is "only a small body of evidence currently relating to the effectiveness of weighted blankets,"⁷⁷ Ms. Berry testified that the use of a weighted blanket would be a relatively common treatment strategy for use in occupational therapy. According to Ms. Berry, the use of a weighted blanket would be a possible treatment strategy for an occupational therapist to consider when treating clients with a range of conditions including chronic pain, sleep disorders, anxiety, autism spectrum disorder, ADHD and PTSD.⁷⁸ As Ms. Berry phrased it, a weighted blanket is something that would found in the "toolbox" of an occupational therapist since weighted blankets are minimally invasive, cost-effective and easy to use, although some caution must be exercised, especially with individuals having communication difficulties, impaired respiration or impaired cognition.⁷⁹

[49] Ms. Berry briefly described how use of a weighted blanket could alleviate symptoms for a range of conditions.⁸⁰ She has personally used weighted blankets in her practice to treat individuals with chronic pain, PTSD, anxiety and sleep disorders.⁸¹

[50] On cross-examination, Ms. Berry testified that other items or strategies, besides a weighted blanket, would be found in the toolbox of an occupational therapist.⁸² She conceded that the premise for the benefits of weighted blankets remains a theory underpinned by relatively little scientific evidence and

⁷⁴ Exhibit AP-2018-054-18 at 3.

⁷⁵ *Ibid.* at 3-4; *Transcript of Public Hearing* at 51-53.

⁷⁶ *Transcript of Public Hearing* at 49.

⁷⁷ Exhibit AP-2018-054-18 at 4.

⁷⁸ *Ibid.*; *Transcript of Public Hearing* at 44-48, 49-53.

⁷⁹ Exhibit AP-2018-054-18 at 3-4; *Transcript of Public Hearing* at 45-47.

⁸⁰ Transcript of Public Hearing at 56-58.

⁸¹ Exhibit AP-2018-054-18 at 3.

⁸² *Transcript of Public Hearing* at 60-61.

that the possible efficacy of a weighted blanket is assessed by an occupational therapist, on a case-by-case basis.⁸³

[51] Where a weighted blanket is used by an individual with insomnia or a sleep disorder, the weighted blanket replaces the bedding or blanket that would be otherwise used.⁸⁴

[52] Ms. Berry notes that there are several types of weighted blankets available in the market and that an Internet search reveals "numerous online vendors of weighted blankets targeting parents of children with special needs and therapists working with individuals with special needs . . ."⁸⁵ In her written report, Ms. Berry states that she has inspected the DreamAway Blanket and found it to be "similar" to the weighted blankets used by her and some of her colleagues.⁸⁶

[53] During direct examination, counsel for Osiris asked Ms. Berry about design considerations underpinning the DreamAway Blanket. Her answer seemed to have been derived, at least in part, from the testimony given by Mr. Kulkarni.⁸⁷ As Ms. Berry's expertise does not extend to product design or manufacture, the Tribunal accords no weight to that small portion of Ms. Berry's evidence.

[54] Otherwise, the Tribunal found Ms. Berry to be a frank and forthright witness who provided evidence that was fair and objective.

POSITIONS OF THE PARTIES ON APPEAL

Osiris

[55] The advance ruling and appeals therefrom proceeded on the uncontested premise that the DreamAway Blanket was classified as an article of bedding within the scope of heading no. 94.04. Shortly before the oral hearing, Osiris revised its position in order to assert that Chapter 94 (Furniture; bedding, mattresses, mattress supports, cushions and similar stuffed furnishings . . .) was irrelevant to the goods in issue.

[56] Instead, Osiris argued that the DreamAway Blanket should be classified under tariff item no. 3926.90.90 as "[0]ther articles of plastics and articles of other materials of heading Nos. 39.01 to 39.14" because the goods are composite in nature. They are comprised of plastic pellets enclosed by a textile shell.

[57] Chapter 39 covers "[p]lastics and articles thereof" with heading no. 39.26 being directed to "[o]ther articles of plastics". Chapter 63 covers "[t]extiles and Textile Articles." Within Chapter 63, Osiris contends that heading no. 63.07, "[o]ther made up articles, including dress patterns," is relevant to the DreamAway Blanket.

[58] As both heading nos. 63.07 and 39.26 refer to part of the goods, Osiris says both headings are equally specific in describing the goods. The plastic pellets serve as the blanket's stuffing and provide the weight attributable to the overall item. As such, the plastic pellets are responsible for the

⁸³ *Ibid.* at 62, 66.

⁸⁴ *Ibid.* at 61-62, 67-68.

⁸⁵ Exhibit AP-2018-054-18 at 3.

⁸⁶ *Ibid*.

⁸⁷ *Transcript of Public Hearing* at 55-56.

functionality of the blanket, and thus its essential character. Accordingly, Osiris argues that the DreamAway Blanket falls to be classified within heading no. 39.26.

[59] Regardless of whether the DreamAway Blanket is properly classifiable within heading no. 39.26 or 94.04, Osiris submits that the goods qualify for the duty-free exemption provided by tariff item no. 9979.00.00.

[60] Osiris says that weighted blankets may assist with sleep quality by: (a) reducing cortisol levels which counteract nighttime production of melatonin, which can in turn adversely affect sleep; (b) enabling production of melatonin; and (c) promoting the release of "happiness hormones" such as serotonin and dopamine within the body.

[61] Moreover, the use of a weighted blanket may alleviate stress and anxiety caused by conditions such as autism spectrum disorder, ADHD, and PTSD.

[62] Osiris asserts that the evidence on the appeal demonstrates that the DreamAway Blanket was specifically designed to alleviate the effects of several disabilities, even though the product may be used by individuals without a disability.

CBSA

[63] After providing an overview of the statutory framework of the *Customs Tariff*, the CBSA submits that the issue of whether goods qualify for the exemption from duty provided by tariff item no. 9979.00.00 is a question of fact. Osiris bears the burden of proof of establishing facts that bring the DreamAway Blanket within the ambit of tariff item no. 9979.00.00.

[64] The CBSA says that an appellant must put its best foot forward and avoid splitting its case by introducing new issues at a late stage, which the CBSA asserts Osiris has done in this appeal.

[65] The CBSA submits that the test for relief from duty requires proof that the goods in issue were specifically designed to assist persons with disabilities and that the goods were specifically designed to assist such persons in alleviating the effects of those disabilities. To meet that test, there must be documentary evidence of a purposeful intent during the design phase of the product.

[66] The CBSA goes on to argue that Osiris has provided no evidence demonstrating the requisite intent. Its evidence is confined to articles referencing weighted blankets in general, as opposed to the DreamAway Blanket in particular. There is no evidence showing that the manufacturer made efforts to research, design or develop a product directed to the specific needs of a disabled person, or that the DreamAway Blanket conforms to any standard that is directed to assisting persons with disabilities.

[67] The CBSA further contends that no rational connection has been shown between the design of the DreamAway Blanket and alleviation of disability, much less that alleviation of disability has actually occurred.

[68] As such, the CBSA argues that there is insufficient probative or credible evidence to prove the facts needed to meet the test for the relief provided by tariff item no. 9979.00.00.

ANALYSIS

[69] Osiris's appeal is brought pursuant to subsection 67(1) of the *Customs Act*, which provides that a "person aggrieved" by a decision of the CBSA may appeal that decision to the Tribunal by filing a notice of appeal within the prescribed timeframe.

[70] The crux of this appeal is Osiris's claim to the duty-free exemption provided by tariff item no. 9979.00.00 which, if granted, would presumably trigger repayment of past duties paid by Osiris to the CBSA. This is sufficient to make Osiris a "person aggrieved,"⁸⁸ which is undisputed by the CBSA.

[71] The first issue for determination is the classification of the DreamAway Blanket within the *Customs Tariff.*

Statutory Framework

[72] Sections 10 and 11 of the *Customs Tariff* prescribe the analytical approach that the Tribunal must adopt when determining how goods are to be classified:

10 (1) Subject to subsection (2), the classification of imported goods under a tariff item shall, unless otherwise provided, be determined in accordance with the General Rules for the Interpretation of the Harmonized System and the Canadian Rules set out in the schedule.

. . .

(2) Goods shall not be classified under a tariff item that contains the phrase "within access commitment" unless the goods are imported under the authority of a permit issued under section 8.3 of the *Export and Import Permits Act* and in compliance with the conditions of the permit.

11 In interpreting the headings and subheadings, regard shall be had to the Compendium of Classification Opinions to the Harmonized Commodity Description and Coding System and the Explanatory Notes to the Harmonized Commodity Description and Coding System, published by the Customs Co-operation Council (also known as the World Customs Organization), as amended from time to time.

[73] The *General Rules* are intended to be applied pursuant to a sequential, hierarchical analysis of the goods, as described by the Supreme Court of Canada in *Canada (Attorney General) v. Igloo Vikski Inc.*⁸⁹

[74] In performing this analysis, section 11 of the *Customs Tariff* requires that the Tribunal also consider the Explanatory Notes to the Harmonized Commodity Description and Coding System, as may be relevant and applicable to the goods in issue.

⁸⁸ Danson Décor Inc. v. President of the Canada Border Services Agency (25 September 2019), AP-2018-043 (CITT) [Danson Décor] at paras. 75-79.

⁸⁹ 2016 SCC 38 [*Igloo Vikski*] at paras. 19-29.

[75] The headings at issue are reproduced below:

94.04 Mattress supports; articles of bedding and similar furnishing (for example, mattresses, quilts, eiderdowns, cushions, pouffes and pillows) fitted with springs or stuffed or internally fitted with any material or of cellular rubber or plastics, whether or not covered.

39.26 Other articles of plastics and articles of other materials of headings **39.01** to **39.14**.

63.07 Other made up articles, including dress patterns.

[76] General Rule 1 provides as follows:

1. The titles of Sections, Chapters and sub-Chapters are provided for ease of reference only; for legal purposes, classification shall be determined according to the terms of the headings and any relative Section or Chapter Notes and, provided such headings or Notes do not otherwise require, according to the following provisions.

[77] On application of General Rule 1, the Tribunal finds that the goods at issue fall squarely within the wording of heading no. 94.04. The goods at issue are a blanket and are labelled as such. On any conventional definition, a blanket is an article of bedding.⁹⁰ It is an article that would be placed on a bed and used to cover a sleeping person.

[78] In both its evidence and argument, Osiris has emphasized throughout that the DreamAway Blanket is useful for enhancing better sleep, up to and including the mitigation of sleep disorders such as insomnia. Those arguments are undermined, if not wholly contradicted, by an assertion that the DreamAway Blanket is *not* an article of bedding, as a person with insomnia or other sleep disorder would be sleeping in a bed (or at least attempting to). In her testimony, Ms. Berry indicated the importance of "sleep hygiene" in the treatment of sleep disorders,⁹¹ and also confirmed that a weighted blanket would replace a blanket or other bedding article that would otherwise be used by an individual.⁹²

[79] The nature of the article, or its description, does not change merely because it may, in some circumstances, be used in other places or contexts besides a bedroom or have other secondary uses than being placed on a bed. This applies to both weighted and non-weighted blankets.

[80] Moreover, the Tribunal agrees with the CBSA that the DreamAway Blanket is not a mere aggregation of different materials. The blanket comprises plastic pellets enclosed within a textile shell. Those elements act in combination to provide a utilitarian article whose functionality exceeds the sum of its parts.

[81] Although the goods can be described as an "article of bedding," they also fall within the wording of heading no. 94.04 as being a "similar furnishing (for example, mattresses, quilts, eiderdowns, cushions, pouffes and pillows) fitted with springs or stuffed or internally fitted with any

⁹⁰ The Tribunal considered the definition of the term "bedding" in the *Merriam-Webster* dictionary, i.e. "the sheets and blankets that are used on a bed;" Exhibit AP-2018-054-44 at 55.

⁹¹ Exhibit AP-2018-054-18 at 3-4; *Transcript of Public Hearing* at 60-61.

⁹² *Transcript of Public Hearing* at 61-62.

material or of cellular rubber or plastics, whether or not covered." Each of those items are characterized by an exterior shell (typically of a textile material) that is stuffed or filled with another material, which may comprise plastic. That fully describes the DreamAway Blanket.

[82] None of the relevant chapter or explanatory notes contradict or limit this conclusion. As such, heading no. 94.04 fully describes the DreamAway Blanket in its entirety. Where the goods meet the description provided in a heading upon application of Rule 1, that finding is dispositive and there is no resort to the remaining rules.⁹³ That is the case here. Accordingly Rules 3(a) and (b) do not come into play, as would be required in order to arrive at the classification as proposed by Osiris.

[83] As there is no dispute concerning the subheadings and tariff item within heading no. 94.04, the Tribunal finds that the DreamAway Blanket is properly classifiable under tariff item no. 9404.90.10.

[84] The Tribunal now turns to a consideration of whether the DreamAway Blanket qualifies for the duty-free exemption provided by tariff item no. 9979.00.00. As noted above, the wording of that provision changed effective January 1, 2019. The goods at issue were imported before that date.

[85] There is a presumption that changes in statutory language are intended to be remedial and to effect some change in the law.⁹⁴ However, the presumption is rebuttable. In supplementary written materials,⁹⁵ the CBSA has provided copies of legislative background materials that purport to show that the amendments to tariff item no. 9979.00.00 were intended to be of a housekeeping nature and not to change the substantive law or the position of anyone who is an importer or an exporter.

[86] There appears to be no disagreement as between the parties concerning the test to be applied in relation to tariff item no. 9979.00.00, as between the old and new versions of that provision. As the importation of the goods in issue predates the amendments to tariff item no. 9979.00.00, the Tribunal need not consider the effect, if any, of the changes in terminology for the purposes of deciding this appeal.

[87] Appeals to the Tribunal are determined *de novo*,⁹⁶ even though one or both parties may elect to carry forward all or part of the record at first instance, to supplement that record with new evidence, or create a new one. The Tribunal must reach its own decision concerning the correct tariff classification for the goods. In doing so, the Tribunal is free to assess the record before it, up to and including the reweighing of evidence placed before the CBSA and giving consideration to any new evidence that may be presented on appeal. The Tribunal owes no deference to the CBSA's decision.⁹⁷

[88] Osiris bears the burden of proof to demonstrate that the CBSA has wrongly denied relief from payment of duties, as provided in tariff item no. 9979.00.00.⁹⁸

[89] In order for goods to qualify as duty-free under tariff item no. 9979.00.00, there must be evidence that the goods were "specifically designed" to assist persons with disabilities; that the specific design is intended to alleviate the effect of disability; and that this result is achieved. The

⁹³ Igloo Vikski at para. 45.

⁹⁴ *R v. Ulybel Enterprises Ltd.* [2001] 2 SCR 867 at para. 34.

⁹⁵ Exhibit AP-2018-054-44.

⁹⁶ Canac Marquis Grenier Ltée, 2017 CanLII 149270 (CA CITT) at para. 27; Danson Décor at paras. 91-93.

⁹⁷ *Danson Décor* at paras. 82-93.

⁹⁸ *Customs Act*, s. 152.

applicable test was summarized by the Tribunal in *Toolway Industries v. President of the Canada Border Services Agency:*⁹⁹

[32] As held in *Sigvaris*,^[100] the Tribunal must therefore determine (1) whether the goods in issue are specifically designed to assist persons with disabilities, and (2) whether the goods in issue are specifically designed to assist such persons in alleviating the effects of those disabilities. In other words, there must be evidence that a design is purposefully related to the alleviation of the effect of disabilities, and there must be some evidence that the goods live up to the claim that they make.

[33] With respect to the second part of the test, the Tribunal has consistently held that compliance with generally recognized accessibility standards (also referred to as barrier-free standards) can be indicative of the fact that the product was specifically designed to assist persons with disabilities in alleviating the effects of those disabilities. As the Tribunal noted in *Globe Union*:^[101]

[E]vidence of compliance of the goods in issue with the barrier-free standards is sufficient in this case to show that the goods in issue were specifically designed to assist persons with disabilities in alleviating the effects of those disabilities. The goal of tariff relief under tariff item No. 9979.00.00 is not to reward the first inventor, but rather to ensure that goods intended to assist persons with disabilities and designed to that effect can enter into Canada free of tariffs. It is not necessary to reinvent the wheel each and every time.

[34] Where a good satisfies the second part of the test by complying with such standards, an appellant must also show that there was purposeful intent to comply with those standards, in order to meet the first part of the test. Documentation showing such purposeful intent during the design phase of a product would normally constitute the best way of demonstrating such intent, but the Tribunal has acknowledged that evidence may also be led from various sources, which only need to be probative and convincing.

[Footnotes omitted]

[90] Osiris relies on the anecdotal documents obtained from Internet searches which discuss the use of weighted blankets in a variety of therapeutic contexts to purportedly show that weighted blankets can be beneficial to individuals with disabilities.

[91] Information that is publicly available and easily retrievable from the Internet is not automatically admissible as evidence. Although evidence obtained from the Internet may be admissible, it must still be scrutinized for reliability. In the case of unofficial websites or those of unknown authorship, the reliability of the information should be assessed by considering the sources and its objectivity, the existence of independent corroboration, and whether the information may have been modified or otherwise changed from a previous version.¹⁰²

⁹⁹ AP-2018-056, 2020 CanLII 34938 (CA CITT).

¹⁰⁰ Sigvaris Corporation v. President of Canada Border Services Agency, AP-2007-009 (CITT) [Sigvaris].

¹⁰¹ Globe Union Canada, 2019 CanLII 110870 (CA CITT) [Globe Union].

¹⁰² *Rona Inc.* AP-2018-053 (CITT) at para. 109.

[92] Several of the documents submitted by Osiris appear to originate from unknown websites or appear to be third-party marketing material. The Tribunal gives little or no evidentiary weight to these documents as being probative, as there is little basis to assess reliability. The Tribunal accords some degree of weight to those documents which appear to be articles published in peer-reviewed scientific journals.

[93] As noted in *Sigvaris*,¹⁰³ disability is present where an individual is assessed as being restricted or lacking in ability to perform his or her normal activities. In the context of disability, the Tribunal has adopted the dictionary meaning of the word "alleviate" as meaning ". . . to lighten, or render more tolerable, or endurable¹⁰⁴

[94] Having regard to the testimony of Ms. Berry, the Tribunal finds that there is some evidence that weighted blankets may assist in the alleviation of some aspects of disability in some individuals with respect to conditions such as autism and PTSD. There is insufficient evidence to support a generalized finding that sleep disorder, including insomnia, necessarily constitutes a "disability."

[95] The evidence also indicates that weighted blankets may be used by individuals without disabilities, for relaxation and other purposes which may confer health benefits.¹⁰⁵ The Tribunal agrees with Osiris that beneficial use of the goods by persons without disability does not automatically operate to remove the goods from the duty relief contemplated by tariff item no. 9979.00.00.¹⁰⁶

[96] However, there are a wide range of goods that may be beneficially used by persons with disabilities and which may also be useful to those without disabilities in the course of day to day life. It is not contemplated that all of such goods should be consequently free from duty.¹⁰⁷

[97] The threshold to be met is that the goods be "specifically designed" to assist persons with disabilities. There must be evidence to demonstrate an intent that the goods were specifically designed to assist persons with disabilities. If that primary intent is present, the goods may qualify for duty relief, and the fact that the goods may also be useful to persons without disability is immaterial or secondary.¹⁰⁸

[98] In other words, goods that are specifically designed for use in alleviating the effects of disability may qualify for a duty-free exemption, even if the product may also be useful to persons without disabilities. The converse does not apply. Goods for use by the general population do not qualify for duty relief merely because of attributes that may be advantageous to persons with disabilities. The starting point is whether there was a demonstrated intent to specifically design a product to assist persons with disabilities by alleviating the effects of disability.

¹⁰³ At para. 42.

¹⁰⁴ *Ibid.*

¹⁰⁵ See, for example, Exhibit AP-2018-054-27 at 26-30.

¹⁰⁶ See Wolseley Canada Inc v. President of the Canada Border Services Agency [Wolseley], 2013 CanLII 91955 (CA CITT) at paras. 41-45.

¹⁰⁷ The provisions of tariff item No. 9979.00.00 need not be given a broad, liberal or expansive reading. See *Sigvaris* at para. 29.

¹⁰⁸ Masai Canada Limited v. Canada Border Services Agency, 2011 CanLII 93730 (CA CITT) [Masai] at para. 21; affd 2012 FCA 260.

[99] There is some evidence that weighted blankets are promoted to the general public as a wellness product.¹⁰⁹ A product that may assist sleep quality may be purchased and used by persons without disability. As there are many types of weighted blankets on the market, there is a gap in the evidence that the Tribunal declines to bridge. Some weighted blankets may be useful in alleviating the effect of disability, but it cannot be presumed that *all* weighted blankets have that utility, in view of the highly personal and customizable therapies used by occupational therapists.

[100] In this case, the Tribunal finds that there is insufficient evidence to demonstrate that the DreamAway Blanket was specifically designed to assist persons with disabilities in order to alleviate the effects of disability. The Tribunal accepts that Osiris may market this product to persons with disabilities. It is also a reasonable inference that Osiris sourced this particular product in order to target consumers who might be interested in acquiring a weighted blanket, whether due to disability or otherwise.

[101] However, neither of these objectives demonstrates a conscious intent to specifically *design* a product with the specific purpose of assisting persons with disabilities. A finding that there was an intent to "specifically design" cannot be made wholly on the basis of a hindsight analysis – there must be evidence that the requisite intent was present at the outset of the product's creation.¹¹⁰

[102] There is no probative evidence showing that Osiris identified particular problems faced by individuals with disabilities and then embarked on a process to create a product with features or attributes tailored to address or mitigate those problems.

[103] As noted in *Masai*,¹¹¹ there must be evidence of a rational connection between the specific product design, the claim to alleviation of disability and the results achieved.

[104] The scientific literature filed by Osiris in support of its appeal discusses "weighted blankets" in general. That evidence does not show a connection with the specific product (DreamAway Blanket) being imported by Osiris, the design of that particular product and how its attributes are specifically designed or tailored to alleviate the effects of disability. At least one such scientific paper states that there is a need for more systematic and objective studies concerning the benefits of weighted blankets for sleep.¹¹² Moreover, there are many types of weighted blankets and the design attributes of those products are likely relevant to the sensations experienced by the user and thus, the overall effect of the blanket:

There are many weighted blankets and vests on the market with different designs, for example, those with metal chains or covers filled with small plastic balls or pellets. Chain covers and ball quilts may provide different sensations (e.g. tactile, thermal insulation) and have different weights, which need to be adapted individually, as some patients may be more sensitive to stimulation, thus requiring a lesser-weighted blanket. The effectiveness of a weighted blanket has been found to relate to the mass of a person¹¹³

¹⁰⁹ For example, Exhibit AP-2018-054-27 at 26-30.

¹¹⁰ *Masai* at paras. 21-22.

¹¹¹ At para. 21.

¹¹² Exhibit AP-2018-054-27 at 13.

¹¹³ *Ibid.* at 17-18.

[105] The conference presentation given at the 2007 Annual Conference of the American Occupational Therapy Association by Tina Champagne et al. covers variable attributes as between individual models of weighted blankets available on the market, namely:

- The amount of weight offered
- Fabric choices
- Weight distribution
- The ability to adapt the amount of weight used in each blanket (or not)
- Materials used as weights
- Ease of the ability to launder
- Ease in ability to change the amount of weight preferred¹¹⁴

[106] The Champagne presentation also identifies various safety and risk concerns pertaining to weighted blankets and their use, such as:

- Diagnostic considerations
- Trauma history
- Respiratory precautions
- Cardiac/circulatory precautions
- Vital signs influence
- Skin integrity including open wounds or fragile skin
- Any lifting precautions
- Orthopedic considerations: broken or fractured bones¹¹⁵

[107] Ms. Champagne further mentions the relative lack of research and the need for additional research.¹¹⁶

[108] Ms. Berry's evidence confirms that the research and theory underpinning the use of weighted blankets is still at a relatively early stage, but that several models of weighted blanket are available on the market. She confirms that the DreamAway Blanket is "similar" to weighted blankets that she has used in her practice, but not that she has actually used the specific model of weighted blanket marketed by Osiris that is at issue in this appeal.

[109] There is no persuasive evidence that specific aspects or variables of weighted blankets, as identified in the scientific literature, were considered or specifically taken into account when designing the product specifications of the DreamAway Blanket and if so, how the product features were created, selected or adapted for use by persons with disabilities to alleviate the effects of disability, as opposed to use by the general population at large.¹¹⁷

[110] Osiris emphasizes product certifications for the DreamAway Blanket that were provided by its supplier. However, that evidence does not assist Osiris.

¹¹⁴ *Ibid.* at 162.

¹¹⁵ *Ibid.* at 160-161.

¹¹⁶ *Ibid.* at 163-166.

¹¹⁷ The marketing materials provided by Osiris's Chinese supplier suggest that the product offered and supplied to Osiris is a copy of a third-party product referred to as "Gravity" but there is likewise no evidence that the Gravity product was specifically designed for use by persons with disabilities for the purpose of alleviating the effects of disability. See Exhibit 27 at 125.

[111] Claims for duty relief under tariff item no. 9979.00.00 have succeeded in situations where a nexus is shown between the functional characteristics of the product and a recognized third-party standard that specifically prescribes product standards directed to the needs of persons with disability, such as the *Americans with Disabilities Act (ADA)*.¹¹⁸ That evidence is not present in this case.

[112] The certifications submitted by Osiris are unrelated to any standards that are tailored to the particular needs of persons with disabilities or to the alleviation of the effects of disability. Moreover, they are irrelevant to demonstrate the intent to design the DreamAway Blanket as a product contemplated by tariff item no. 9979.00.00 as being eligible for tariff relief.

[113] The OEKO-Tex[®] Standard 100 certificate¹¹⁹ is dated February 6, 2018, and thus post-dates Osiris's request for an advance ruling from the CBSA, which was filed on December 27, 2017.¹²⁰ Consequently, it does not provide evidence of design intent with respect to alleviation of disability at the time of product creation, as the product already existed and was the subject matter of an advance ruling request. Even if the timing were not an issue, the certificate goes no further than confirming that the textile used by Osiris's supplier complies with a "human ecological" safety threshold with respect to dyes, colourants and the absence of lead content in textile materials intended to have direct contact with human skin. Such issues of product safety are of general application consistent with consumer protection requirements for vendible products – there is no nexus with respect to any product feature that clearly pertains to any disability, much less its alleviation.

[114] The second certification is a test report from the testing laboratory SGS.¹²¹ This document reports that testing of the plastic pellets used as filling for the DreamAway Blanket comply with the requisite standards for lead-free substrate material. The Tribunal finds that this is also a general manufacturing standard that would (or at least should) be followed in the manufacture of goods, regardless of the end user. Lead-free plastic pellets would not be a unique or special indicator that the product is specifically designed for use by persons with disabilities, as this would connote, at least by implication, that the use of plastic containing lead would be otherwise acceptable for products that are intended for use by persons without disabilities. Put another way, the absence of lead in the plastic components of the DreamAway Blanket does not distinguish that product as being specifically designed to alleviate the effects of a disability.

[115] The third certification originates from CELAB[®]. This document is dated July 7, 2018.¹²² Therefore, the certification originated well after the DreamAway Blanket had been imported and while Osiris's appeal for reconsideration of the advance ruling denying relief from duty was pending before the CBSA's Recourse Directorate. The certification expresses the following conclusion:

After inspection of the technical documentation issued by the customer and in his request, we express our opinion that the product meets the technical requirement of the following directives and standards: 93/42/EEC Medical devices (MDD).¹²³

¹¹⁸ Wolseley; BSH Home Appliance Ltd., 2014 CanLII 149588 (CA CITT) [BSH]; Globe Union.

¹¹⁹ Exhibit AP-2018-054-27 at 51.

¹²⁰ *Ibid.* at 46.

¹²¹ *Ibid.* at 57.

¹²² *Ibid.* at 60, 61-100.

¹²³ *Ibid.*

[116] As indicated above, evidence that the goods are specifically designed for use by people with disabilities to alleviate the effects of disability must exist from the outset of product design. The effects of successful product performance may be demonstrated after the fact, but the evidence of purposeful design intent must exist in the mind of the manufacturer from the outset of product creation and cannot be created retroactively.¹²⁴

[117] More importantly, this certificate does not establish that the DreamAway Blanket is a medical device, much less that it is an item that has been specifically designed for the purposes defined by tariff item no. 9979.00.00. The boundaries of the testing reported by CELAB[®] are only directed to assessing risk management and quality control measures used in Kuangs's manufacturing premises.

[118] Excerpts from the International Organization for Standardization (ISO) standards catalogue relevant to the CELAB[®] certification have been filed with the Tribunal.¹²⁵ Osiris has highlighted various passages in this material,¹²⁶ especially those referable to the term "medical device". The presence of the words "medical device" *per se* in the document does not prove that the weighted blanket manufactured by Kuangs for Osiris is, in fact, a medical device. This amounts to cherry-picking certain passages in a document, creating a contextual mosaic and then inviting the Tribunal to draw a conclusion favourable to the appellant based on that compilation. This strains credulity and undermines the overall credibility of the evidence that has been filed.

[119] When the CELAB[®] document is given a purposive reading in context, it shows only that Kuangs uses certain risk-management and quality controls for the manufacturing processes carried out in its facility that comply with *certain* standards required of facilities engaged in the manufacture of medical devices, per EEC requirements.

[120] The conclusion expressed by CELAB[®] is limited in scope and says only that Kuangs uses a conformity template, has generated test reports in accordance with prescribed standards, provides a product instruction manual and uses the designation "CE" on the product label. These parameters demonstrate that Kuangs manufactures products uniformly, i.e. one weighted blanket will be consistent and uniform relative to another with respect to product specifications. It does not establish that those product specifications are responsible for any therapeutic effect that would support a regulatory licence for a medical device, much less create a nexus with a therapeutic use or benefit relative to any particular condition or disability.

[121] Accordingly, Osiris's evidence concerning standards pertain to *certain aspects* of quality control and best manufacturing practices. While those standards would apply to the manufacture of a medical device, the certification goes no farther than that. It falls well short of showing that Kuangs is actually a medical device manufacturer or that the goods in issue are a medical device. Regulatory approval for medical and therapeutic devices is conferred by government authority (such as Health Canada), not by private testing laboratories such as CELAB[®]. Mr. Kulkarni has testified that Osiris has not sought regulatory approval from Health Canada with respect to the DreamAway Blanket.

¹²⁴ BSH at para. 66; *Sigvaris* at paras. 35-37.

¹²⁵ Exhibit AP-2018-054-27 at 61-100.

¹²⁶ As well as the two other certifications/test reports from Oeko-Tex[®] and SGS.

[122] For these reasons, the standards referenced by CELAB[®] are of general application¹²⁷ and clearly distinguishable from standards that are formulated to address and mitigate challenges, symptoms or effect of disability. As such, the standards relied upon by Osiris are unlike the ADA standards considered by the Tribunal in, for example, *Globe Union* and *Wolseley*.

[123] With respect to the import quote sheets submitted by Osiris, the Tribunal finds that these are commercial documents prepared for the purpose of securing a price quote or placing an order for the goods. They are dated in late 2017 and coincide approximately with the time frame when the DreamAway Blanket was first imported. Although the product specifications for the goods proposed to be ordered must be described for these commercial purposes, the document content does not speak to the process of product design, which would be necessarily antecedent to placing a commercial order.

[124] Although Mr. Kulkarni testified that the dimensions of the DreamAway Blanket were critical, there is no supporting documentary evidence to illustrate a purposeful intent during the process of product design reflecting this aspect of the product and how it relates to addressing or alleviating disability or its effects.

[125] Osiris submitted that the DreamAway Blanket is equipped with a "carrying case" that is a useful attribute as it enables the goods to be easily transported from place to place, which may assist persons with disabilities. Upon closer review, the Tribunal finds that the "carrying case" is the original product packaging supplied by Kuangs in the form of a zippered polyvinyl chloride (PVC) bag with handles.¹²⁸ Such a bag could be discarded, after purchase, or it could be retained to either store or transport the weighted blanket.

[126] Left unanswered is whether the bag is designed for convenient use by a person with disabilities. At point of purchase, the DreamAway Blanket is folded and packed within the zippered PVC bag. The Tribunal questions whether the weighted blanket, once removed from the bag, could be readily refolded and repacked within the confines of the PVC bag without difficulty, especially by a person with a disability, given the size and weight of the item. The evidence indicates that caution is required when using weighted blankets, especially since they may be cumbersome to move or handle.

[127] The zippered PVC bag likely facilitates transport of the DreamAway Blanket from point of purchase to the user's home or destination. This denotes a convenience factor of general application to all purchasers and not one that is necessarily focused on persons with disability. Beyond that, there is no evidence that the bag has been designed to incorporate features that would facilitate its use by persons with disability.

[128] A legal burden of proof is discharged where the party bearing that onus demonstrates to a court or tribunal that the outcome that he seeks is more likely to be correct than not (balance of probabilities), based on an assessment of all of the evidence that has been tendered.¹²⁹

¹²⁷ Avoidance of lead or the use of corrosive or carcinogenic chemicals, solvents or dyes in consumer products or their manufacture.

¹²⁸ Exhibit AP-2018-054-27 at 9.

¹²⁹ For example, *F.H. v. McDougall*, [2008] 3 SCR 41 at paras. 40-49; *Morrison v. The Queen*, 2018 TCC 220 at paras. 65-89.

[129] In assessing whether an evidentiary burden has been discharged, a court or tribunal considers the relevant information and opportunity possessed by a party in terms of its ability to lead evidence in order to prove a particular fact.¹³⁰

[130] In this case, there are apparently other documents pertaining to the design of the DreamAway Blanket, namely correspondence, drawings, photographs, draft specifications and factory drawings.¹³¹ None of this material was filed by Osiris, ostensibly for reasons of "legal strategy".¹³² Having regard to the test¹³³ governing the application of tariff item no. 9979.00.00, the Tribunal considers that such documents would be highly relevant to an assessment as to whether the requisite purposeful intent to specifically design a weighted blanket to assist persons with disability was present at the relevant time.

[131] A party will be expected to prove those facts falling squarely within its knowledge or means of knowledge, especially where the requisite facts or information are not within the power, possession or control of the opposing party.¹³⁴ As Osiris has claimed that its own personnel was responsible for designing the DreamAway Blanket, in conjunction with Kuangs, the supporting documentation would be within the possession or control of Osiris. The Tribunal consequently draws a negative inference from the failure to file that material.

[132] Osiris has the burden of proof to demonstrate that the CBSA was wrong in denying relief from duty according to the provisions of tariff item no. 9979.00.00. Having considered the evidence and submissions of the parties, the Tribunal is not persuaded that the burden of proof has been discharged. Accordingly, the appeal must be dismissed.

DECISION

[133] The appeal is dismissed.

Susan D. Beaubien

Susan D. Beaubien Presiding Member

 ¹³⁰ See for example *Snell v. Farrell*, 1990 CanLII 70 (SCC), [1990] 2 SCR 311; *Canadian Northern Quebec R. Co. v. Pleet*, 1921 CanLII 518 (ON CA), 50 O.L.R. 223, affd 1921 CanLII 564 (SCC), [1923] 4 DLR 1112; *Hoffmann-La Roche Ltd. v. Apotex Inc.* (1984), 1984 CanLII 1883 (ON CA), 47 O.R. (2d) 287 at 288.

¹³¹ *Transcript of Public Hearing* at 27.

¹³² *Ibid.* at 28.

¹³³ For example, *Masai*; *Toolway*.

¹³⁴ Ibid. See also, for example, Canada v. Anchor Pointe Energy Ltd., 2007 FCA 188 at paras. 35-36; re J. Humber, AP-2018-062 (CITT) at paras. 84-87.