

Reproduced with permission from Medical Devices Law & Industry Report, 8 MELR 730, 10/29/2014. Copyright © 2014 by The Bureau of National Affairs, Inc. (800-372-1033) <http://www.bna.com>

Certifications Under the Trade Agreements Act: 10 Tips to Avoid TAA Traps for the Unwary



BY ROGER GOLDMAN, DAVID HAZELTON, ANNE ROBINSON, DAVID TOLLEY AND SHIRA EPSTIEN

On September 3, 2014, U.K.-based medical device maker Smith & Nephew (the “Company”) agreed to pay \$8.3 million (plus an additional \$3 million in attorney’s fees) to resolve a lawsuit filed under the federal civil False Claims Act (the “FCA”) due to alleged misrepresentations by the Company regarding the origin of certain products it sold to the U.S. Departments of Defense (“DoD”) and Veterans Affairs (the “VA”)(8 MELR 612, 9/17/14). The relator in the case was Samuel Cox, an information technology executive for the Company who was terminated shortly before he filed his suit under the FCA. Smith & Nephew joins a lengthening list of companies targeted under the FCA for issues related to non-compliance with the federal Trade Agreements Act (the “TAA”). Relators and their lawyers have continued to drive TAA enforcement actions since the early part of the decade, bringing FCA cases against a widening variety of companies, including businesses in the industrial supply, furniture, hardware, and home improvement industries.¹ Based on the Smith & Nephew settlement, we expect that medical de-

vice and other health care supply companies may be next.²

The TAA generally requires companies that sell products to government agencies to certify that all “end products” sold are made (i) in the United States or a designated country or (ii) “substantially transformed” in the United States or a designated country prior to purchase.³ Major non-designated countries include China, India, Malaysia, Thailand and others. Many companies that sell products to the United States government may have supply relationships with non-designated countries.

Numerous traps for the unwary exist under the TAA, and failure to observe relatively straightforward certification requirements can lead to substantial liabilities.⁴ In addition to bid protests and product substitution investigations, entities face potential liability under the FCA—which allows for treble damages plus penalties—to the extent any such certification is false or inaccurate (i.e., a false or inaccurate certification may be viewed as constituting a “false” claim for payment that, if known, would not have been paid by the govern-

¹ Home Depot settled an FCA case alleging violations of the TAA for \$2.25 million in 2011, and Samsung settled a similar case in 2013 for \$2.3 million.

Roger Goldman and David Hazelton are partners with Latham & Watkins.

Anne Robinson, David Tolley and Shira Epstein are associates with the firm.

² See Brendan Pierson, “Smith & Nephew to pay \$11 mln in whistleblower suit,” Reuters (Sept. 4, 2014), available at <http://www.reuters.com/article/2014/09/04/smith-nephew-settlement-idUSL1N0R52KA20140904>.

³ For a complete list of TAA Designated Countries as of September 2013, see: <http://www.va.gov/oal/business/fss/taa.asp>. Some examples include Australia, Canada, Hong Kong, Japan, Mexico, Singapore and many others.

⁴ See 19 U.S.C. § 2512(a)(2). The TAA provides narrow exceptions for product purchases from non-designated countries when there are no eligible domestic or designated country products or where the supply of domestic or designated country products is too small to support the government’s needs.

ment). Accordingly, medical device manufacturers doing business with the government should carefully review their current and possible TAA certifications and establish internal policies and procedures to ensure compliance with the TAA throughout the life of their government contracts.

1. Smith & Nephew: First TAA Settlement Involving Medical Device Manufacturers

Smith & Nephew is a global medical technology business that manufactures devices in four main categories of injuries or ailments: (1) orthopedics reconstruction; (2) advanced wound management; (3) sports medicine; and (4) trauma and extremities. The Company has 14 manufacturing plants worldwide, with facilities in the United States, the United Kingdom, Germany, Switzerland, Beijing, Suzhou, and several other locations around the world.

Cox filed his *qui tam* complaint in December of 2008 in the Western District of Tennessee, alleging that, from 2007 through 2008, Smith & Nephew sold the government orthopedic devices that it had bought from Malaysia-based Straits Orthopaedics while certifying in its federal supply agreements that all of its end products were made in the United States.⁵

Notably, Smith & Nephew disclosed voluntarily in September of 2008 to DoD and the VA that some of the medical tools it previously sold to both Departments did not comply with the TAA's country of origin requirements. Specifically, the Company disclosed that it supplied products that were made in non-designated countries, including Malaysia, Thailand and China, and that it may, therefore, have supplied incorrect country of origin certifications in its supply contracts.⁶

In April 2010, Smith & Nephew filed a motion to dismiss Cox's complaint based on the FCA's public disclosure bar and Rule 9(b). Notably, Cox survived the motion to dismiss despite the fact that the Company had previously disclosed the conduct at issue to the DoD and VA. The court denied the motion. First, it ruled that the disclosure to the DoD and VA was not "public," following a growing number of circuits, including the First, Ninth, Tenth and Eleventh, in construing the FCA's public disclosure bar narrowly.⁷ Second, in the eyes of the court, Cox pled the alleged fraud with the requisite particularity despite his inability to identify any specific false claim. As the court stated –

Relator does not point to the specific dates of the improper transactions or such details as serial or tracking numbers for falsely designated products sold to the government, but to require such information in the present case would demand an omniscience that cannot reasonably be expected of a relator's complaint. Indeed, the scheme alleged is so expansive and involved that Relator cannot fairly be expected to identify every fraudulent act it entails.⁸

⁵ See Amended Complaint at 7, U.S. ex rel. Samuel Adam Cox III v. Smith & Nephew, Inc., No. 2:08-cv-02832 (W.D. Tenn., order of dismissal, Sept. 4, 2014).

⁶ See Order Denying Defendant Smith & Nephew, Inc.'s Motion of Dismissal at 13, U.S. ex rel. Samuel Adam Cox III v. Smith & Nephew, Inc., No. 2:08-cv-02832 (W.D. Tenn., order of dismissal, Sept. 4, 2014).

⁷ *Id.*, at p. 16.

⁸ *Id.*, at pp. 19-20.

2. History of Qui Tam Relator Activity Involving the TAA

Though the first of its kind for a medical device manufacturer, the Smith & Nephew settlement is a recent example of a lengthy industry-by-industry history of robust *qui tam* relator lawsuits under the FCA based on alleged false country of origin certifications under the TAA. *Qui tam* relator actions under the FCA to date alleging false country of origin certifications under the TAA were first concentrated in the office supply industry, followed by the information technology ("IT") industry. There have also been a small number of cases in other industries, including furniture and industrial supply.

Marking the beginning of the trend, *qui tam* relators filed several suits against office supply companies with government contracts in 2003.⁹ These suits alleged that the contractors falsely certified that products they were selling to governmental agencies were U.S. made or produced in TAA-compliant countries.¹⁰ These suits ultimately settled in 2005 and 2006, each with multi-million dollar fines, including Office Max for \$9.4 million, Office Depot for \$4.75 million and Staples for \$9.4 million.¹¹ The 2003 series of suits were particularly shocking to the federal contracting community given the small federal market share held by the accused companies.¹²

The IT industry came next. Between 2009 and 2012, several FCA cases alleging TAA-noncompliance against IT companies were settled or otherwise concluded.¹³ Relators in the IT cases had mixed success; some resulted in settlement agreements (for example, *Océ North America, Inc.* settled for \$1.2 million in 2009), but many were dismissed on procedural grounds.¹⁴

Now, with the Smith & Nephew case, the first medical device manufacturer has settled an FCA suit alleging false country of origin claims. Other device manufacturers importing items from Malaysia and other non-designated countries may face suits with similar allegations. Moreover, it would not be surprising to see increased government enforcement activity under the TAA as the government learns more about the medical device manufacturing process. And, given the significant pay out to the Relator in the Smith & Nephew case, potential whistleblowers may bring more *qui tam* suits if they believe they stand to make millions of dollars just for bringing such suits, even if the suits are settled and not litigated to judgment.

⁹ Ron R. Hutchinson, *Oversight of GSA Federal Supply Schedule Contracts: From Internal Compliance Programs to Civil False Claims Actions*, 37 Pub. Cont. L.J. 569, 572 (2008).

¹⁰ *See id.*

¹¹ *See id.* at 573.

¹² Angela B. Styles et al., *GSA Trade Agreements Certification: An Ambush for Commercial Providers*, 41 SPG Procurement Law 15, 15 (2006).

¹³ *See, e.g.*, United States ex rel. Crennen v. Dell Marketing L.P., 711 F. Supp. 2d 157 (D. Mass. 2010); United States ex rel. Folliard v. CDW Technology Services, Inc., 722 F. Supp. 2d 20 (D.D.C. 2010); United States ex rel. Dugan v. ADT Security Services, Inc., 2009 WL 3232080 *10 (D.Md. 2009); United States ex rel. Folliard v. Synnex Corp., 2011 WL 2836372 (D.D.C. July 19, 2011); United States ex rel. Sandager v. Dell Marketing, L.P. et al., Civil No. 08-4805 (D. Minn. Apr. 26, 2012).

¹⁴ 72 F. Supp. 2d 174 (D.D.C. March 25, 2011).

3. Overview of TAA Applicability and Key Requirements

A. TAA requirements apply broadly to federal agency sales.

The TAA, and the need to certify a product's origination as in the United States or a designated country, applies to virtually all federal agency supply contracts in excess of \$204,000.¹⁵ Annex 1001.1a-2 of the North American Free Trade Agreement contains the list of the many federal agencies subject to the TAA. Agencies listed there include the Department of Justice, the Department of Labor, the Department of Veterans Affairs, the National Science Foundation and many others.

These federal agencies broadly interpret the \$204,000 threshold. The "estimated value" is calculated based on the estimated total value of a contract, including options. Additionally, nearly all multiple award schedule sales are subject to the TAA, as agencies such as the General Services Administration ("GSA") have taken the position that because the value of each multiple award schedule contract exceeds the threshold, the TAA is applicable to all such contracts.¹⁶ Thus, all items on the GSA Schedule, the VA Federal Supply Schedule, and the NASA SEWP contracts must comply with the TAA. The TAA also applies to medical supply contracts awarded under DoD's Distribution and Pricing Agreement program.¹⁷

There are some narrow exceptions to the applicability of the TAA, such as contracts in which there is no eligible domestic or designated country product or where the supply of domestic or designated country products is too small to support the government's needs.¹⁸ The contracting agency is responsible for determining whether a product is unavailable from TAA-compliant countries, resulting in agencies such as the VA and DoD needing to make their own non-availability determinations for their own contracts. Finally, the TAA does not apply to small business set-asides or sole-source acquisitions.

B. Country of origin certifications.

During the contracting process, sellers of products to government agencies subject to the TAA must certify that any "end product" they sell is either (i) "wholly the growth, product or manufacture" of the United States or a designated country or (ii) "has been substantially transformed into a new and different article of commerce" with a distinct "name, character, or use" in that country.¹⁹ In particular, federal contracts will require a seller to certify as a condition to any supply agreement "that each end product . . . is a U.S.-made or designated country end product" or to list explicitly any end products that are not U.S.-made or made in a designated country.²⁰

C. Meaning of end product.

"End products" are generally defined as "those articles, materials and supplies to be acquired for public

use."²¹ However, different governmental agencies interpret the meaning of "end product" differently. For example, some agencies take the position that every line item in a purchase contract constitutes an "end product" for purposes of TAA compliance, despite the fact that numerous line items may relate to a single product. Furthermore, some line items are not themselves manufactured products—rather, they may be upgrades or custom applications made to another line item. For this reason, other agencies have explicitly recognized that they cannot require TAA compliance for line items representing upgrades or customizations to another line item (e.g., line item for a custom paint job). Significantly, the Office of the United States Trade Representative has not taken an official regulatory position on this issue, but has provided informal advice that if a contract as a whole exceeds the relevant dollar amount threshold, then each line item product is subject to the TAA.²²

D. Substantial transformation.

To the extent medical device companies utilize end products from non-designated countries (as many do), these companies will need to consider carefully whether work they undertake with these products amounts to "substantial transformation" for purposes of the TAA. According to the TAA, an article is "substantially transformed" when it is "a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed."²³ The "substantial transformation" test is fact-specific and looks to the totality of the circumstances, but no legal authority has defined at a technical level what changes qualify a product as "substantially transformed" into a U.S. or designated country product for purposes of the TAA.²⁴ Generally, the relevant factors are the country of origin for the item's components, the extent of processing that occurred within each country and whether any such processing rendered a product with a new name, character and use.

While the Smith & Nephew case is the first *qui tam* settlement involving TAA-based false country of origin claims for medical devices, U.S. Customs and Border Protection ("CBP"), the agency tasked with country of origin determinations under the TAA, has issued at least five final determinations regarding product origin issues for medical devices.²⁵ For example, in July 2014 CBP issued a country-of-origin decision for a medical

²¹ See FAR § 52.225-5(a).

²² See, e.g. *Tic-La-Dex Business Systems, Inc.*, B-235016.2, 89-2 CPD ¶ 323, 1989 U.S. Comp. Gen. LEXIS 1061 (U.S. Comp. Gen. 1989).

²³ See 19 U.S.C. § 2518(4)(B)(ii).

²⁴ See *Xerox Corp. v. United States*, 753 F. Supp. 2d 1355 (2011). In *Xerox Corp.*, the Court of International Trade (CIT) confirmed its jurisdiction to review U.S. Customs and Border Protection decisions applying the substantial transformation test to determine a product's country of origin for government procurement purposes. The CIT did not explain, however, how to conduct a substantial transformation analysis. Instead, it merely affirmed CBP's finding that the printer toner cartridges at issue were not sufficiently transformed in New York to qualify as a U.S.-made end product.

²⁵ See, e.g., Customs Ruling No. H24881 (July 8, 2014); Customs Ruling No. N098319 (Apr. 5, 2010); Customs Ruling No. HQ560561 (July 24, 1997); Customs Ruling No. N251416 (Apr. 9, 2014); Customs Ruling No. HQ558009 (Nov. 10, 1994).

¹⁵ See FAR 25.1101(c).

¹⁶ See Ordering Guidelines, U.S. General Services Administration (Sept. 10, 2014), available at <http://www.gsa.gov/portal/category/100639>.

¹⁷ See *id.*

¹⁸ See 19 U.S.C. § 2512(a)(2).

¹⁹ See 19 U.S.C. § 2518(4)(B).

²⁰ See FAR § 52.225-6.

device that interfaces with a breath monitor and concluded that all relevant end products were manufactured in designated countries despite limited assembly operations in a non-designated country.²⁶

In general, CBP looks to the following six factors to determine the country of origin for an end product: (i) the country of origin of the article's components; (ii) the extent of the processing that occurred in each country; (iii) whether the processing gave the product a new name, character, or use; (iv) the resources expended on product design and development; (v) the extent and nature of post-assembly inspection procedures; and (vi) the skill required during the manufacturing process.²⁷ Case law and CBP rulings indicate that neither very simple assembly operations,²⁸ testing, inspecting, cleaning, or packaging of articles,²⁹ nor taking apart an article and putting it back together³⁰ qualify as substantial transformation. To the extent companies wish to

²⁶ See Customs Ruling No. H24881 (July 8, 2014). In this somewhat unique case, the manufacturer was concerned that the assembly operations in the non-designated country could result in substantial transformation of the article from a designated country end product to a non-designated country end product. CBP concluded no substantial transformation had occurred and noted that for substantial transformation determinations, the "key issue is the extent of operations performed and whether the parts lose their identity and become an integral part of the new article."

²⁷ HQ H095409 (Sept. 29, 2010) (ruling that the United States was the country of origin for solar photovoltaic panels despite the fact that the individual raw and manufactured materials originated in twelve different countries because of the "complex and meaningful" assembly operations, the significant percentage of U.S.-made parts, and the research and development conducted in the United States).

²⁸ See, e.g., *Ran-Paige Company, Inc. v. United States*, 35 Fed. Cl. 117 (1996) (ruling that a contractor who added handles to Chinese cookware did not "substantially transform" the cookware); *In re CSK International, Inc.*, U.S. Comp. Gen. Proc. Dec., B-278111.2, 1997 U.S. Comp. Gen. LEXIS 486 (U.S. Comp. Gen. 1997) (finding that a contractor who assembled tools in the United States by attaching a U.S. handle to a Chinese tool head did not substantially transform the tool head by adding the handle).

²⁹ See, e.g., *Appeal of Ballantine Lab., Inc.*, ASBCA No. 35138, 88-2 B.C.A. (CCH) P20,660, 1988 ASBCA LEXIS 75 (A.S.B.C.A. Mar. 7, 1988) (ruling that the contractor that inspected, tested, and packaged products made in Taiwan did not substantially transform the product despite the contractor's offer to disassemble and reassemble the articles in the U.S.); *TRS Research*, B-283342, 99-2 Comp. Gen. Proc. Dec. P85, 1999 U.S. Comp. Gen. LEXIS 188 (rejecting the claim that cleaning, inspecting, repainting, and attaching minor parts to foreign-made steel containers substantially transformed the containers).

³⁰ See, e.g., *Appeal of Ballantine Lab. See also General Kinetics, Inc., Cryptek Division*, B-242052.2, 70 Comp. Gen. 473, 91-1 Comp. Gen. Proc. Dec. P445, 1991 U.S. Comp. Gen. LEXIS 836 (finding that a contractor who disassembled a fax machine manufactured in a non-designated country and reassembled it by adding significant necessary components substantially transformed the fax machine, while a different fax

rely on substantial transformation of products they obtain from non-designated countries, they will want to take a critical look at the extent of their transformative work with these products.

4. Ten Recommendations to Help Avoid the TAA's Traps for the Unwary

1. Take inventory of your federal supply schedules and other government contracts to assess whether all items that could be viewed as "end products" were properly designated for TAA purposes.
2. Identify the country of origin for all such products and assess whether you have any potential end products from non-designated countries. Ensure you are aware of the most up-to-date "Designated Country" list, which is found at FAR 25.003.
3. For any potential non-designated country end products, assess whether you undertake any transformative activities with respect to these products.
4. Develop clear internal policies and procedures designed to ensure that non-designated country products undergo substantial transformation prior to entry into your product supply chain.
5. Implement a system to track country of origin information for all of your end products.
6. Consider obtaining an advisory opinion or formal determination of origin for TAA purposes from CBP to confirm the substantial transformation of specific products. However, be mindful that an adverse ruling or opinion regarding products you are currently selling to federal agencies may well require a voluntary disclosure and other remedial measures.
7. Seek guidance in published rulings from CBP on substantial transformation determinations that may be relevant to your products.
8. Ensure that any sourcing changes for manufacturing operations or finished goods purchases are evaluated for potential impact on country of origin determinations.
9. Obtain adequate country of origin representations and indemnity from any manufacturers.
10. If necessary, seek clarification from the Contracting Officer as to which contract line item numbers (CLINs) are subject to the TAA in a given solicitation, and/or include clarifying language with your proposal regarding how you are defining end products.

machine was not substantially transformed where only one circuit board and a few other small components were altered).