ORIGIN OF THE PIECES: HOW TO DETERMINE A PHARMACEUTICAL PRODUCT'S "COUNTRY OF ORIGIN"

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What is a pharmaceutical product's "country of origin?" Companies that manufacture drugs and medical devices are confronted with this question every time they label a product, import it, export it, market it, or sell it to the Federal Government. Unfortunately, the answer to this question is not as simple as many would think. Moreover, the correct answer depends on who is asking.

The origin of a product is obvious when all the materials and labor used to manufacture a product originate in one country. Typically, however, that is not economically feasible or even possible. As Milton Friedman, the Nobel Prize-winning economist, frequently remarked: "No one country can make a pencil."[1] A pencil seems to be such a simple product, yet its manufacture requires thousands of people extracting and processing materials from every corner of the globe. The pencil's cedar shaft may come from lumber cut and milled in the Pacific Northwest; the lead from graphite mined in Sri Lanka; the eraser from rubber and oils extracted from plants in Malaysia, along with pumice from Italy; the brass coupling from zinc and copper mined in Peru. And this is just the beginning. There are far more material and labor inputs involved, including various lacquers and resins used to label the pencil and give it its characteristic shiny yellow finish. Miraculously, this complex arrangement of raw materials, labor, and expertise combines to produce a pencil that retails for only ten cents. Milton Friedman used this example to demonstrate certain principles of the free market price system, but it also illustrates why it is no simple task in the modern era to determine a product's country of origin.

The good news is that one can determine which country's input predominates under a country of origin standard. The bad news is that different regulatory agencies employ entirely different country of origin standards, which often yield different country of origin determinations for the same product. The result has been confusion and frustration—especially in the pharmaceutical sector. This Article seeks to ease some of the confusion and frustration by providing an overview of the principal regulatory schemes, their country of origin standards, and how they apply in the pharmaceutical context. The hypothetical fact pattern that follows will help illustrate each of these points.

I. HYPOTHETICAL FACT PATTERN

In this hypothetical, a company named PharmCo manufactures a sterile injectable drug named BrandX. To manufacture BrandX, PharmCo takes the active pharmaceutical ingredient (API), which it imports from India,

1. Friedman attributed this illustrative example to Leonard E. Read, *I, Pencil*, THE FREEMAN, Dec. 1958.

and subjects it to a costly series of processing procedures in its U.S. laboratory. These procedures include testing, filtering, mixing the API with U.S.-sourced excipients, and measuring out specified dosages. The resulting drug is then placed into special syringes that are manufactured in the United States. The syringes and other U.S.-made components account for fifty-two percent of the overall cost of the components in BrandX; the Indian-sourced API accounts for the remaining forty-eight. PharmCo packages the finished product with labeling that identifies PharmCo's U.S. laboratory as the place of manufacture and states that the product is "Made in the USA." PharmCo markets and sells BrandX in the United States, including sales to the government via a Federal Supply Schedule (FSS) contract. PharmCo also exports BrandX to numerous foreign markets.

So, what is BrandX's country of origin? Caution: the short answer may cause dizziness. To begin with, the place of business of the manufacturer is in the United States; therefore, for the purpose of Federal Drug Administration (FDA) labeling requirements, PharmCo's U.S. address should be listed on the BrandX label. Under U.S. Customs and Border Protection (CBP) regulations, however, BrandX is a product of India and should be marked accordingly. When exporting BrandX to foreign countries, it will be a product of the United States under many, but not all, foreign trade agreements affecting the duties owed in the destination country. With regard to government procurement, BrandX is a product of India and thus is generally ineligible for high-value government contracts (i.e., at or above $204,000), but qualifies for sale as a "domestic end product" under lower-value government contracts (i.e., $3000 to $204,000).[2] Finally, under U.S. consumer protection laws, the representation "Made in the U.S.A." is considered misleading and cannot appear anywhere on the product or its marketing materials.

Such divergent results produce confusion and frustration because one intuitively expects the legal status of an item to remain constant unless the underlying facts change. Yet, here, BrandX's country of origin—with all the legal implications of that status—seems like a moving target. Keep in mind, however, that the various regulatory schemes that require country of origin determinations do so for very different policy purposes. And regulators with different aims are apt to adopt different standards geared towards those aims. Regulated entities like pharmaceutical manufacturers, therefore, must treat country of origin questions in different regulatory contexts as being distinct questions.

II. FDA LABELING REQUIREMENTS

There is no requirement under the Federal Food, Drug and Cosmetic Act (FDCA) or FDA regulations for drug manufacturers to identify a pharmaceutical product's "country of origin." FDA requirements, however, are critical to country of origin determinations in two principal respects. First, a

2. *See infra* note 62 and accompanying text.

drug will be deemed "misbranded" if "its labeling is false or misleading in any particular,"[3] including representations on the label about the product's country of origin that may be required under CBP regulations (discussed *infra*).

Second, the FDA requires each drug label to "bear conspicuously the name and place of business of the manufacturer, packer, or distributor."[4] The FDA defines a "manufacturer" as one who performs mixing, granulating, milling, molding, lyophilizing (i.e., freeze-drying), tableting, encapsulating, coating, or sterilizing, as well as filling dispensing containers with aerosol or gas drugs.[5] This FDA labeling requirement differs from the CBP's country of origin marking requirement. In fact, the "place of business of the manufacturer" is quite often located in a country that is different from the "country of origin" marked for CBP purposes. Under FDA regulations:

> If a person manufactures, packs, or distributes a drug or drug product at a place other than the person's principal place of business, the label may state the principal place of business *in lieu of* the actual place where such drug or drug product was manufactured or packed or is to be distributed, unless such statement would be misleading.[6]

Therefore, a product manufactured primarily in a French laboratory may be labeled with both a CBP marking that reads "Made in France" as well as a New Jersey address that indicates the "place of business of the manufacturer."

In the case of BrandX, PharmCo's choice to list its principal U.S. place of business on the label is FDA compliant, regardless of BrandX's country of origin. The inclusion of "Made in the U.S.A.," however, on the label constitutes misbranding under FDA regulations because, as discussed below, this representation is misleading and inconsistent with the marking regulations administered by CBP, the government procurement rules under the Trade Agreements Act (TAA), and the consumer protection laws administered by the Federal Trade Commission (FTC).

III. THE "SUBSTANTIAL TRANSFORMATION" STANDARD

The "substantial transformation" standard is the test that CBP uses to determine (1) how a product should be marked under the Tariff Act of 1930, which requires all products of *foreign* origin to be marked with the country of foreign origin, and (2) whether a product is eligible for government procurement under the TAA, which gives a preference to products made in the United States and certain designated countries.[7] Before discussing the role of country of origin determinations in these two different regulatory contexts, let us turn to the substantial transformation test that they share in common.

3. 21 U.S.C. § 352(g) (2012).
4. 21 C.F.R. § 201.1(a) (2014).
5. *Id.*
6. *Id.* § 201.1(j) (emphasis added).
7. 19 C.F.R. §§ 134.1(b), 177.22 (2014).

A. *General Principles of Substantial Transformation*

Under the substantial transformation test, a product's country of origin is the place in which it is produced, manufactured, or substantially transformed.[8] When a product consists of materials and labor from more than one country, the country of origin is the place where the materials have been "substantially transformed into 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."[9] In making determinations and advisory rulings on a product's country of origin, CBP considers the totality of the circumstances, including the origin of the product's components, the extent of the processing that occurs within a given country, and whether such processing renders a product with a new name, character, and use. The most basic characteristic of a "substantial transformation" is a manufacturing process that changes the foreign components' essential use through complex and meaningful processes. Mere assembly, for example, does not generally amount to substantial transformation.[10] To understand how these principles apply to pharmaceutical products, it is important to look specifically at CBP's past rulings.

B. *Applying the Substantial Transformation Test to Pharmaceutical Products*

In applying the substantial transformation test to pharmaceutical products, CBP closely scrutinizes the manufacturing process of those products. For products that are the result of chemical manufacture, the analysis focuses largely on the extent to which the finished product retains the essential identity and character of the API. The cases summarized *infra* illustrate the main principles that have guided CBP's rulings.

1. Processing Pharmaceutical Products from Bulk Form into Measured Doses Does *Not* Constitute Substantial Transformation

CBP made clear in Customs Ruling HQ 561975 that substantial transformation does not take place when pharmaceutical products are simply processed from bulk form into measured doses.[11] In this case, the anesthetic drug sevoflurane was imported into the United States in bulk and processed into dosage form though various testing, filtering, and packaging operations.[12] CBP determined that the imported sevoflurane was not substantially transformed in the United States because it retained its chemical and physical properties after the U.S. processing.[13] Nor did the processing in the

8. *Id.* § 2518(4)(B).
9. 19 U.S.C. § 2518(4)(B); 19 C.F.R. § 177.22(a).
10. U.S. Customers and Border Protection (CBP) has long held that simple assembly procedures are not enough to substantially transform the components of an article into a new and different article of commerce. *See, e.g.*, HQ Ruling Letter 082747 (Customs & Border Prot. Feb. 23, 1989). All CBP rulings can be found at http://rulings.cbp.gov/index.asp.
11. HQ Ruling Letter 561975 (Customs & Border Prot. Apr. 3, 2002).
12. *Id.*
13. *Id.*

United States result in a change in the product's use because the imported bulk sevoflurane had a predetermined medicinal use as an inhalable anesthetic drug.[14] Finally, CBP noted that there was no change in name, as the product was identified as sevoflurane in both its bulk and processed forms.[15]

Similarly, in HQ 561544, CBP determined that the process by which geneticin selective antibiotic was made by filtration of a solution of geneticin sulfate in bulk powdered form and purified water did not constitute a substantial transformation.[16] This process primarily involved removing impurities from the bulk chemical and repackaging it.[17]

2. Simply Altering the Delivery Mechanism of the Drug Does *Not* Constitute a Substantial Transformation

In HQ 562889, CBP held that the process by which lasoprazole (imported from Italy) was given an enteric coating did not constitute a substantial transformation.[18] CBP acknowledged that the enteric coating altered the delivery rate of the drug into the human body as it prevented dissolution from stomach acid in order to reach the intestines and be absorbed by the body.[19] CBP emphasized, however, that the lasoprazole had the same name, chemical abstract number, medicinal use, and chemical and physiological properties both before and after processing. The country of origin, therefore, was the country in which the API was manufactured: Italy.

Similarly, in HQ 733248, CBP examined whether Immune Globulin (Human) Fraction II paste (Fraction II paste) of U.S. origin was substantially transformed as a result of processing in Belgium that allowed it to be used intravenously—a faster, more effective delivery mechanism than intramuscular injection, which is how the unprocessed paste was used.[20] The paste was processed by sterile filtering and buffering, then filled into vials and freeze-dried.[21] CBP determined that the paste did not undergo a substantial transformation in Belgium because the "paste [was] the major part of the end product although the minor processing performed in Belgium was necessary to make the final product usable in intravenous form."[22] Interestingly, CBP relied in part on *National Juice Products v. United States*,[23] in which the Court of International Trade (CIT) held that imported orange juice concentrate

14. *Id.*
15. *Id.*
16. HQ Ruling Letter 561544 (Customs & Border Prot. May 1, 2000).
17. *Id.*
18. HQ Ruling Letter 562889 (Customs & Border Prot. Jan. 21, 2004).
19. *Id.*
20. HQ Ruling Letter 733248 (Customs & Border Prot. Aug. 22, 1990).
21. *Id.*
22. *Id.*
23. 10 Ct. Int'l Trade 48 (1986), *superceded by statute*, Customs Modernization Act, Pub. L. No. 103-182, 107 Stat. 2057 (1993), *as recognized in* Precision Specialty Metals, Inc. v. United States, 24 Ct. Int'l Trade 1016 (2000).

was not substantially transformed by the addition of water, orange essences, and oils because the "very essence" of the product had not changed.

Finally, in N.Y. C85112, CBP considered the country of origin marking of a single-dose administration kit of Lupron Depot (leuprolide acetate for depot suspension), used "in the treatment of advanced prostatic cancer."[24] The API, a synthetic analog of leuteinizing hormone-releasing hormone (LHRH), was exported from the United States to Japan, where it was encapsulated into sterile microspheres and placed in a dual-chamber syringe.[25] The purpose of microencapsulating the leuprolide acetate was to "modify the delivery rate of the drug into the body from the daily-dosage form."[26] CBP found, however, that the fundamental character of the leuprolide acetate remained unchanged by the processing and, therefore, the country of origin of the syringes remained as the United States.

3. Substantial Transformation Often *Does* Occur When Multiple APIs Are Combined or When Processing Causes Chemical Changes to the API That Result in a Product with a New Character, Name, or Use

In HQ 563207, CBP found that a substantial transformation had occurred when two active pharmaceutical ingredients used in the treatment of diabetes, pioglitazone HCl and metformin, were combined to produce Actoplus Met.[27] The finished product showed significantly increased effectiveness in the treatment of type 2 diabetes compared to either active ingredient taken alone.[28]

Processes that clearly affect a change in chemical properties also can constitute substantial transformation. For example, in *Drexel Chemical Co. v. United States*, the CIT found that the herbicide Diuron was substantially transformed due to the physical changes that air milling of Diuron cake induced.[29] In particular, the size of the Diuron particles was reduced and the chemical properties changed as valence bonds were freed during air milling.[30] While the Diuron molecule remained unchanged throughout the process, the physical and chemical changes to the Diuron cake resulted in a final, usable herbicide.[31] Without the additional processing, the court found that plant leaves were unable to take in the Diuron particles, rendering the Diuron unusable for its intended purpose.[32] Thus, CBP found that the air milling resulted in a substantial transformation.[33]

24. N.Y. Ruling Letter C85112 (Customs & Border Prot. Mar. 27, 1998).
25. *Id.*
26. *Id.*
27. HQ Ruling Letter 563207 (Customs & Border Prot. June 1, 2005).
28. *Id.*
29. 27 Ct. Int'l Trade 804, 810 (2003).
30. *Id.*
31. *Id.*
32. *Id.*
33. *Id.* at 811.

4. Substantial Transformation *May* Occur When Processing Significantly Increases the Effectiveness of the Final Product

Unfortunately, CBP precedents are less consistent when the basis for substantial transformation is that the processing of API is complex and results in a *more effective* final product. In fact, CBP's position on this issue appears to have shifted over time, as demonstrated by the following two cases.

In 1989, CBP analyzed the question of whether raw vancomycin hydrochloride is substantially transformed when it is "process[ed] into a purified, finished antibiotic drug capable of intravenous use by humans."[34] The API, vancomycin hydrochloride, was imported in bulk from Japan.[35] The importer then processed the raw API in the United States by (1) testing for potency, adding more active ingredient if necessary; (2) treating it with nitrogen gas to prevent processing degradation; (3) dissolving and filtering it into a solution; (4) testing for pyrogenicity (i.e., heat production); and (5) freeze-drying it in glass vials as part of a three-stage process: freezing, heating, and water extraction.[36]

CBP held that the importer's processing substantially transformed the API because it transformed a "raw substance unfit for human use" into "an injectable antibiotic fit for human use."[37] CBP also found that "the character of the raw substance changes from a powder of variable potency to a purified solution of uniform potency levels."[38] Finally, CBP noted that the final product underwent a change in name ("Sterile Vancomycin Hydrochloride U.S.P."), demonstrating that considerable processing was necessary to qualify the product as "sterile"; the U.S. Pharmacopeia suffix "indicates adherence to a standardized composition for the finished product."[39]

Ten years later, CBP took a narrower approach to what level of processing is required to substantially transform raw API. In HQ H073995, CBP addressed whether the API, metoprolol succinate, was substantially transformed in Sweden, where it was processed to make Toprol-XL.[40] The manufacturing process entails the creation of metoprolol succinate beads "by spraying a solution of metoprolol onto cores to create uniformly sized beads."[41] The metoprolol beads are then coated with a polymer solution.[42] Next, the coated metoprolol succinate beads are mixed with excipients (inac-

34. *See* HQ Ruling Letter 731731 (Customs & Border Prot. Feb. 23, 1989).
35. *Id.*
36. *Id.*
37. *Id.*
38. *Id.*
39. *Id.* at 2. *See also* HQ Ruling Letter 563301 (Customs & Border Prot. Aug. 26, 2005) (raw parathormone was substantially transformed from an unstable, nonsterile, frozen material unsuitable for human use into a pharmaceutical agent ready for human use).
40. HQ Ruling Letter H073995 (Customs & Border Prot. Oct. 29, 2009).
41. *Id.*
42. *Id.*

tive ingredients) and compressed into tablets.[43] Then, the "tablets are coated with an additional polymer solution and polished prior to packaging."[44] The tablet manufacturing process is more complex and more costly than the process used to produce the API. And yet, despite the complexity of the manufacturing process, CBP held that the metoprolol succinate did not undergo a substantial transformation.[45]

CBP noted that the complexity of the manufacturing process is not, in and of itself, a determining factor.[46] Nor is it sufficient that the process "alter[ed] the delivery rate of the drug or otherwise improv[ed] the delivery mechanism."[47] Although the manufacturer of Toprol-XL claimed that metoprolol succinate was "unusable, if not toxic" in its raw or bulk form, CBP noted that any substance can be toxic if ingested improperly and that altering the dosage or delivery rate of a drug does not constitute a substantial transformation.[48] CBP emphasized that the process must change the character of metoprolol succinate and that, in this case, the final product was merely metoprolol succinate in a measured dose and that the country of origin would be where "the active ingredient was sourced."[49]

As the CBP rulings discussed above demonstrate, the question of a pharmaceutical product's country of origin can be a complex one, especially in the very common scenario in which an API produced in one country is manufactured into a final product in a different country. It is also clear from CBP's decisions that, in the pharmaceutical context, a correct country of origin analysis cannot be achieved without an in-depth understanding of the chemical properties at issue and how they are transformed, if at all, by the numerous processes the manufacturer undertakes to produce a finished drug product. Ultimately, to be deemed substantially transformed, the API should be processed into a final product that has "a new name, character, or use."[50]

C. *Marking Requirements Under the Tariff Act*

Pharmaceutical companies that manufacture and market products using foreign elements must determine whether their products are U.S.- or foreign-made because, under section 304 of the Tariff Act of 1930, all products of foreign origin imported into the United States must be marked with the name of a country of foreign origin.[51] No marking is required, however, if the product is U.S.-made.[52] To determine the proper country of origin for

43. *Id.*
44. *Id.*
45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.*
49. *Id.*
50. *Id.*
51. 19 U.S.C. § 1304 (2012).
52. *Id.*

marking purposes, CBP applies the aforementioned "substantial transformation" test.[53]

Regarding PharmCo's hypothetical BrandX, the API imported from India does not appear to be substantially transformed in the United States. The API undergoes costly, multistep processing in the United States, all of which is necessary to change the raw API into a final product suitable for human consumption. Under CBP's more recent decisions, however, the cost and complexity of processing are not themselves dispositive. Much like Toprol-XL in HQ H073995, the manufacturing process does not change the name, character, or use of the API. BrandX in its final product form is essentially the API in a measured, deliverable dose. Therefore, for the purpose of CBP's marking requirements, BrandX is a product of India and must be marked as such.

If PharmCo fails to properly mark BrandX as a product of India, it faces special marking penalties equal to ten percent of the value of the unmarked goods.[54] Given the high value and sale volume for many pharmaceutical products, such penalties pose a significant risk. Moreover, unlike the penalties for other violations of the Tariff Act, the special marking penalties cannot be mitigated by providing CBP with a prior disclosure of the violation. It is crucial, therefore, for manufacturers to ensure that their products are properly marked with the correct country of origin.

D. *Government Procurement Marking Requirements*

1. The Trade Agreements Act

The substantial transformation test is also used under the TAA to determine whether a product is eligible for government procurement.[55] Specifically, under the TAA, when a supply contract involves finished end products valued at or above $204,000,[56] there is a government preference for goods made in either the United States or certain "designated foreign countries and instrumentalities" listed in FAR 52.225-5.[57] Several major U.S. trading partners, including China and India, are not "designated countries" and,

53. It should be noted that CBP does not apply the substantial transformation test for goods imported under the North American Free Trade Agreement (NAFTA) (i.e., imports from Mexico and Canada). These are subject to a special set of country of origin standards. North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289, art. 415 (1993); 19 C.F.R. pt. 102 (2014). For marking purposes, the NAFTA scheme uses a complex hierarchy of country of origin standards, most of which are "tariff shift" tests (i.e., rules that determine origin based on where a specified change in tariff classification took place). *Id.*

54. 19 U.S.C. § 1304(i).

55. 19 C.F.R. § 177.22.

56. *See* FAR 25.1101(c)(1); Procurement Thresholds for Implementation of the Trade Agreements Act of 1979, 78 Fed. Reg. 76,700 (Dec. 18, 2013) (adjusting the dollar thresholds pursuant to Executive Order 12260). Other thresholds may apply under various free trade agreements.

57. *See also Trade Agreements Act (TAA) Designated Countries*, FED. SCHEDULES, INC., http://gsa.federalschedules.com/Resource-Center/Resources/TAA-Designated-Countries.aspx (last updated Feb. 2014).

therefore, end products originating in those countries are not generally eligible for government acquisitions.[58]

In the case of BrandX, it has been determined that it is a product of India under the substantial transformation standard. Therefore, unless BrandX qualifies for certain exceptions to the TAA preferences (e.g., no comparable product is made in the United States or in a designated country), it is not eligible to be placed on a Federal Supply Schedule for sale to the U.S. Government. When PharmCo sells BrandX to the U.S. Government, it will complete a Trade Agreements Certificate that requires PharmCo to certify that the product it is selling to the government is made in either the United States or a "designated country."[59] False certifications can result in the cancelation of valuable contracts, debarment from federal contracting, and multimillion-dollar fines. In addition to enforcement efforts made by federal agencies, competitors often police each other for compliance. Accordingly, some companies will use bid protests to expose perceived noncompliance with the TAA, putting awards at risk. It is clear, therefore, that an accurate country of origin determination is critical for any entity seeking to market goods to the U.S. Government.

2. The Buy American Act

Unlike the TAA, the Buy American Act (BAA)[60] does not employ the substantial transformation test.[61] The BAA applies to government procurement of manufactured "end products" with an estimated value over $3000 but under $204,000.[62] Under the BAA, preference is given to "domestic end products," which are defined as products manufactured in the United States where the cost of the components mined, produced, or manufactured in the United States exceeds fifty percent of the cost of all its components.[63] The BAA test thus has two separate elements: (1) the end product must be manufactured in the United States and (2) the cost of the end product's *domestic* components must exceed fifty percent of the cost of all the product's components.

3. End Product Manufactured in the United States

The determination of whether an end product is manufactured in the United States is made on a case-by-case basis. The assembly of an end product's components in the United States, as long as it is more than "simple" assembly, will constitute domestic manufacture in most cases. Mere packag-

58. FAR 52.225-5.
59. FAR 52.225-6.
60. 41 U.S.C. §§ 8301–05.
61. *See* FAR 25.101.
62. FAR 2.101; Procurement Thresholds for Implementation of the Trade Agreements Act of 1979, 76 Fed. Reg. 76,808, 76,809 (Dec. 8, 2011) (adjusting the TAA dollar thresholds pursuant to Executive Order 12260).
63. 43 C.F.R. § 12.730; FAR 25.003; *see also* DFARS 252.225-7001(a)(2)(ii).

ing or reassembly of foreign components, for example, does *not* constitute domestic manufacture.[64] Further, not all forms of work on components constitute manufacturing. For example, the Government Accountability Office (GAO) determined that the sterilization of foreign-made surgeons' gloves did not materially alter the form of the gloves and was simply "treatment of the finished product."[65] Accordingly, GAO found the glove sterilization did not constitute "manufacturing" under the BAA.[66]

4. Cost of Domestic Components Exceeds Fifty Percent of Product's Cost

A "component" is defined under the BAA as an "article, material, and supply incorporated directly into an end product or construction material."[67] The country where the component is mined, produced, or manufactured becomes the component's country of origin for purposes of the fifty percent domestic component cost test. There is no subcomponent cost test for determining a component's country of origin. Manufacture of domestic subcomponents into foreign components, however, can change the domestic cost percentage. The cost of any component purchased by a contractor includes transportation costs to the place of incorporation and any applicable duty.[68] For components manufactured by a contractor, all costs associated with the manufacture of the component—including transportation cost and allocable overhead costs but excluding profit—are included in determining the cost of the component.[69] The cost of components, however, does not include any costs associated with the *manufacture of the end product*.[70] Given the complexities of these calculations, savvy government contractors with a strong understanding of the BAA can make production decisions that allow them to comply with the law while still minimizing their production costs.

Even though BrandX is a product of India under the TAA and not substantially transformed in the United States, it nevertheless qualifies as a "domestic end product" under the BAA. First, it is "manufactured" in the United States because the processing of the foreign-sourced API, as well as the manufacture of the syringes, constitutes far more than simple assembly. Second, the syringes and other U.S.-made components account for fifty-two percent of the overall cost of the components in BrandX. Therefore, BrandX qualifies as a domestic end product and can be sold to the U.S. Government under contracts valued at less than $204,000.

64. *See* Rolm Corp., B-200995, 81-2 CPD ¶ 106, at 3 (Comp. Gen. Aug. 7, 1981).
65. *See* Marbex, Inc., B-225799, 87-1 CPD ¶ 468, at 3 (Comp. Gen. May 4, 1987).
66. *Id.*
67. FAR 25.003.
68. *Id. See also* Specialty Plastic Prods., Inc., ASBCA No. 42085-86, 95-2 BCA ¶ 27,895 (applying fifty percent component cost test).
69. FAR 52.225-1(a)(2).
70. *Id.* (emphasis added).

IV. U.S. CONSUMER PROTECTION LAWS

A. *FTC Requirements*

Manufacturers whose pharmaceutical products are "substantially transformed" in the United States may be eager to emphasize this fact on their labels and marketing materials, but beware: a higher standard applies to the use of "Made in the USA" and similar statements. Under U.S. consumer protection laws administered by the FTC, only a product that is "all or virtually all" made in the United States may be accompanied by express or implied representations that the product is made in the United States.[71] CBP only requires a product to be marked with its country of origin when it is foreign-made.[72] Therefore, products that are substantially transformed in the United States, but are not "all or virtually all" made in the United States, can comply with both regulatory standards if they simply contain no country of origin marking.

Manufacturers that wish to emphasize the U.S. origin of their products through labeling and marketing materials may do so in one of two ways. First, an unqualified "Made in the USA" or similar formulation may be used if the "all or virtually all" U.S.-made standard is satisfied.[73] To clear this hurdle, all significant parts and processing that go into the product must be of U.S. origin.[74] "Significant parts" are any elements that present a significant cost component to the final product.[75]

Alternatively, a manufacturer may make a *qualified* statement such as "[seventy percent] U.S. content" or "Made in U.S. of U.S. and imported parts."[76] It is crucial, however, that qualified claims not be deceptive in any respect. If, for example, a product contains only a negligible amount of U.S. parts, it would be misleading to use a qualified statement like "Made in the U.S. of U.S. and imported parts."[77]

In the case of PharmCo's BrandX, the API is manufactured in and imported from India. API is certainly a significant part of the final product and, as such, BrandX is not "all or virtually all" made in the United States. Rather, under CBP marking requirements, BrandX should be labeled as a product of India.

B. *Other Consumer Protection Laws*

In addition to FTC oversight, representations about a product's country of origin can be challenged by competitors as being misleading pursuant to

71. *See* FED. TRADE COMM'N, ENFORCEMENT POLICY STATEMENT ON U.S. ORIGIN CLAIMS (1997), *available at* http://www.ftc.gov/os/1997/12/epsmadeusa.htm [hereinafter FTC POLICY STATEMENT].

72. 19 C.F.R. § 134.11 (2014).

73. *See* FTC POLICY STATEMENT, *supra* note 71.

74. *Id.*

75. *Id.*

76. *See* BUREAU OF CONSUMER PROT., FED. TRADE COMM'N, COMPLYING WITH THE MADE IN USA STANDARD 30 (1998), *available at* http://business.ftc.gov/documents/bus03-complying-made-usa-standard.

77. *Id.*

various statutes and regulations aimed at consumer protection. Under the Lanham Trademark Act, competitors have standing to sue in federal district court for damages and to enjoin the use of any description or representation that misrepresents various aspects of the product, including its "geographic origin."[78] Often, competitors will bring suit, claiming that a product's country of origin is misstated. For example, in *Tube Forgings of America Inc. v. Weldbend Corp*., a U.S. manufacturer of carbon steel pipe fittings challenged its competitor for representing its fittings as U.S.-made.[79] In other cases, however, plaintiffs have made claims under the Lanham Act for what their competitors have failed to state. For example, in *Alto Products Inc. v. Tri Component Corp.*, a U.S. brake shoe manufacturer challenged its competitor for failing to mark its products with the country of origin, which was Israel.[80]

A second venue in which competitors can challenge claims of geographic origin is before the National Advertising Division (NAD), an entity under the Council of Better Business Bureaus, Inc. In one well-known case, the NAD reviewed a dispute arising out of the fact that Russian Standard, maker of Imperia vodka, was making statements on its website and in press releases that its competitor's vodka, Stolichnaya, was "distilled and bottled in Latvia" and "not authentically Russian."[81] The record showed that Stolichnaya vodka is produced at two distilleries, both of which are located in Russia, and all Stolichnaya vodka products are made from Russian wheat, which is distilled with Russian water and Russian yeast.[82] After the vodka has been produced at the Russian distilleries, however, the vodka was sent in bulk to a bottling plant in Riga, Latvia, and, at the bottling plant, the vodka was filtered to remove any particles that may have inadvertently entered the tanks during the shipping process; it was bottled, labeled, and packed in cases for shipment to different markets around the world.[83] Russian Standard argued that filtering and bottling in Latvia detracts from the "Russian-ness" of Stolichnaya.[84] NAD concluded that Russian Standard could question the "Russian authenticity" of Stolichnaya vodka in its advertising, but only if it clearly and adequately disclosed why it believes Stolichnaya vodka is not authentic Russian vodka (i.e., that it is filtered, bottled, and labeled in Latvia).[85] NAD found that the evidence was insufficient to support the statements that Stolichnaya vodka is "distilled" and "made" in Latvia.[86]

78. 15 U.S.C. § 1125(a)(1) (2012).
79. 788 F. Supp. 1150, 1151 (D. Or. 1992).
80. No. 93 CIV. 3076(LMM), 1994 WL 689418, at *1 (S.D.N.Y. Dec. 8, 1994).
81. Russian Standard Vodka, Inc., Case No. 4591 (NAD/CARU Case Reports Jan. 2008), *available at* http://case-report.bbb.org/search/search.aspx?doctype=1&casetype=1.
82. *Id.*
83. *Id.*
84. *Id.*
85. *Id.*
86. *Id.*

A third context in which country of origin claims can be challenged is in lawsuits filed by consumers under various state statutes that prohibit false or misleading advertising. Consumers may bring lawsuits either individually or on behalf of a class of similarly situated persons. For example, an individual can bring a lawsuit to recover damages for being deceived into buying something that he or she believed to be a "pure" German product because of advertising claims that overstate the representation of "Made in Germany." That plaintiff could also seek to represent a class of plaintiffs, thus magnifying the damages prospect exponentially.

The consumer protection laws previously discussed further demonstrate the need for pharmaceutical manufacturers to make accurate country of origin determinations. Moreover, when the country of origin is properly identified, it is equally important not to overstate a product's origin, as illustrated by the various legal disputes that have been waged between competitors and between consumers and manufacturers in federal court, in state court, and before self-regulatory bodies.

V. EXPORT REQUIREMENTS

Pharmaceutical manufacturers that export goods from the United States to foreign markets will frequently receive requests from foreign importers and customs authorities to provide a "U.S. Certificate of Origin." Typically, such a certificate is sought in order to obtain preferential tariff treatment pursuant to a trade agreement between the United States and the foreign country. In other cases, foreign customs authorities may require certificates of origin for the purpose of quotas, antidumping, anticircumvention, statistics, or origin labeling. Unfortunately, there is no uniform country of origin standard for the purpose of such certificates. Each country has its own system of tariffs with its own "rules of origin." Where there is a free trade agreement (FTA) that controls, the signatory countries have typically negotiated special rules of origin for different categories of goods. While the rules of origin vary widely, most fall within the following four types:

1. *Substantial transformation*: Origin is where component(s) are substantially transformed into a new and different product.
2. *Regional value content*: Origin is where a certain minimum percentage of value is added (an ad valorem percentage test).
3. *Tariff shift*: Origin is where a certain shift in classification under the Harmonized Tariff Schedule occurs as a result of the manufacturing.
4. *Specified process*: Origin is where a specific manufacturing or processing operation occurs.

By way of illustration, the following are two scenarios frequently encountered by exporters. When a U.S. pharmaceutical company exports products to the Republic of Korea (Korea), the customs authorities in Korea may request a U.S. certificate of origin to ensure that the goods being imported

qualify for preferential tariff treatment under the FTA it has with the United States.[87] Like many FTAs, the one executed by the United States and Korea contains several different rules of origin that govern how origin is to be determined. These include a series of tariff shift rules that apply for pharmaceutical products. For example, if BrandX is properly classified under the "30.04" heading of the harmonized tariff schedule (HTS), which covers various "Medicaments," but its API prior to processing in the United States is classified under "any other heading," it is considered to originate in the United States.[88] Therefore, a U.S. certificate of origin may be issued.

By contrast, if a U.S. pharmaceutical company is exporting drugs to Qatar, for example, there is no FTA between the United States and Qatar. Therefore, if the exporting company is asked to provide a U.S. certificate of origin, it must investigate the standards applied by the foreign customs authorities requesting the certificate. The Customs Department in the State of Qatar has provided guidance indicating that it considers goods "comprised of a number of components of various origins" to be "made in" the country where the various elements are "assembled."[89] Applying this rather simple "specified process" standard to BrandX, a U.S. certificate of origin would be appropriate because PharmCo brings the Indian API and the U.S.-made components together in the United States to manufacture a finished product.

VI. CONCLUSION

Pharmaceutical companies face a difficult task in determining the country of origin of their products, given the different standards that apply in various regulatory contexts. A pharmaceutical company cannot assume, for instance, that its product qualifies as U.S.-made for the purpose of government procurement or for CBP marking requirements simply because the FDA acknowledges the manufacturer is located in the United States. Nor can a company assume a product is properly labeled "Made in the U.S.A." merely because the product qualifies as U.S.-made under CBP's substantial transformation test. As seen above, the various standards employed by U.S. and foreign agencies often yield different results. Therefore, each country of origin question must be addressed individually, applying the correct standards with great care.

The importance of compliance in this area is evidenced by the severe consequences that can result for noncompliance. If a pharmaceutical company that supplies products to the Federal Government falsely represents its prod-

87. Free Trade Agreement, U.S.–Korea, Annex 6-A, at 6-16, Mar. 15, 2012, *available at* http://www.ustr.gov/trade-agreements/free-trade-agreements/korus-fta/final-text.

88. *Id.*

89. Memorandum from the Qatar Customs Dep't on Qatar Customs Import Regulations, at 3 (on file with author).

ucts as being TAA-compliant, it faces not only the potential loss of a lucrative contract, but the even more troubling prospect of penalties under the False Claims Act, suspension and debarment, or even criminal charges. A company that imports API or other components and fails to mark its products with the correct country of origin may be penalized with "additional duties" equal to ten percent of the appraised value of the final products.[90] And a company that misleadingly suggests its products are "Made in the USA" faces not only the prospect of enforcement from the FTC, such as fines and injunctions, but also liability under the Lanham Act and state consumer protection laws for false advertising.

In several respects, pharmaceutical manufacturers are particularly vulnerable to making noncompliant country of origin determinations. First, pharmaceutical manufacturers are typically subject to the full range of regulatory regimes discussed above, creating a greater risk of error in applying the numerous divergent standards. Second, it is common for pharmaceutical manufacturers to purchase API from multiple sources in different countries, or to switch API suppliers with some frequency, based on price or other business considerations. This creates a circumstance in which the correct country of origin may change over time or even vary from batch to batch. It is vitally important, therefore, that pharmaceutical companies take a fresh look at the country of origin determinations they have made in the past and verify that their present origin determinations are correct and accurately reflected in the labeling and marketing materials. Finally, companies must ensure that their compliance programs incorporate procedures that ensure the appropriate standards are applied, that they are applied correctly, and that they are applied on an ongoing basis to account for major changes in the supply chain.

90. 19 C.F.R. § 134.2 (2014).

Table 1: Summary of Country of Origin Standards

Regulatory Context	Standard	Agency	Statutes/Regulations
Product marking	Substantial transformation For NAFTA, tariff shift	CBP	Tariff Act 19 C.F.R. Part 134
Government contracts (≥$204,000)	Substantial transformation	CBP, GSA, contracting agencies	Trade Agreements Act 19 C.F.R. Part 177
Government contracts ($3000–$204,000)	Manufactured in United States + Cost of U.S. components > 50% cost of all components	GSA, contracting agencies	Buy American Act 48 C.F.R. Part 25
FDA labeling	No COO standard, but COO on label must be accurate. Must also include place of manufacture on label.	FDA	Food Drug & Cosmetic Act 21 C.F.R. Part 201
Export: certificate of origin	Varies by country	Foreign customs authorities	Free trade agreements Foreign customs regulations
Made in the USA/ consumer protection	All or virtually all made in the USA Qualified statements okay if not misleading	FTC	FTC Act enforcement policy statement