UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, DC

In the Matter of	
CERTAIN ANTIVENOM COMPOSITIONS AND PRODUCTS CONTAINING THE SAME	Investigation No. 337-TA-___

VERIFIED COMPLAINT OF BTG INTERNATIONAL INC. UNDER SECTION 337 OF THE TARIFF ACT OF 1930, AS AMENDED

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44	Rose French "Snake Antivenin Drug Maker Stands Out During Hurricanes," The Associated Press, Reproduced in the Cincinnati Post (OH) (January 16, 2006)
45	Ross Kerber, "An Increase in Poisonous Snakebites Feared: Officials Check Antidote Supply," Boston Globe (September 14, 2005).
46	Tony McDonough, "The Runcorn company helping Mr. Bush deal with a vicious reptile" Daily Post (Liverpool) (April 8, 2003).
47	U.S. Patent No. 6,709,655
48	Armentano, et al., "Overview and controversies in the medical management of pit viper envenomation in the dog," Journal of Veterinary Emergency and Critical Care (2011) 461-470.
49	Paniagua-Solis, et al, "From Serotherapy to Fabotherapy," J. Venom. Anim. Toxins, 2011.
50	Hoose et al., "Retrospective analysis of clinical findings and outcome of cats with suspected rattlesnake envenomation in Southern California: 18 cases (2007-2010) J. Vet. Emer. & Critical Care (2013).
51	Sanchez, et al., "Cross reactivity of three antivenoms against North American snake venoms," Toxicon (2003) 315-320.
52	Consroe et al.,. "Comparison of a New Ovine Antigen binding Fragment (Fab) Antiveninn for United States Crotalidae With the Commercial Antivenin for Protection Against Vemon-Induced Lethality in Mice," Am. J. Trop. Med. Hyg. (1995) 507-510.
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I. INTRODUCTION

1. BTG International Inc. ("BTG") respectfully files this Complaint pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, based upon the unlawful and unauthorized importation into the United States, the sale for importation, or the sale within the United States after importation, of certain crotalid antivenom pharmaceutical compositions and products containing the same including, without limitation, the product Antivipmyn, the product Anavip, the product labeled "Antivenin- *Bothrops asper* and *Crotalus durissus*," and all other substantially similar products designated by alternate trade names or labeling formalities that infringe one or more claims of U.S. Patent No. 8,048,414 ("the '414 patent") (collectively, the "Accused Products").[1] Pursuant to Commission Rule 210.12(a)(9)(i), a certified copy of the '414 patent is attached hereto as Exhibit 1. Pursuant to Commission Rule 210(a)(9)(ii), certified copies of the recorded assignments for the '414 patent are attached hereto as Exhibit 2.

2. Proposed Respondents in this matter are Veteria Laboratories, formerly T.I. Salud S.A. de CV, ("Veteria Labs"); BioVeteria Life Sciences, LLC, formerly Veteria Animal Health, LLC, ("BioVeteria"); Instituto Bioclon S.A. de C.V. ("Bioclon"); Laboratorios Silanes SA de CV ("Laboratorios Silanes"); The Silanes Group ("Silanes Group"); Rare Disease Therapeutics, Inc. ("RDT"); and Accredo Health Group, Inc. ("Accredo"). Veteria Labs, BioVeteria, Bioclon, RDT, Laboratorios Silanes, Silanes Group, and Accredo are collectively referenced as the "Respondents."

3. Respondents directly and/or indirectly infringe one or more claims of the '414 patent as identified below and as further detailed in paragraphs 69-185.

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[1] As will be discussed in further detail below, the term "Fab" stands for "Fragment Antigen-Binding" and represents one region, or fragment, of an antibody that binds to antigens (e.g., antigens of proteins in snake venom, which are neutralized when bound by Fab).

4. The asserted claims of the '414 patent are reproduced in the table below.

Claim #	Claim Language
1	An antivenom pharmaceutical composition for treating a snakebite victim, comprising Fab fragments which bind specifically to a venom of a snake of the *Crotalus* genus and which are essentially free from contaminating Fc as determined by immunoelectrophoresis using anti-Fc antibodies, and a pharmaceutically acceptable carrier, wherein said antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the *Crotalus* genus.
2	The antivenom pharmaceutical composition of claim 1, wherein an antibody source for said Fab fragments is IgG(T).
3	The antivenom pharmaceutical composition of claim 1, wherein an antibody source for said Fab fragments is polyvalent IgG(T).
4	The antivenom pharmaceutical composition of claim 1, wherein the Fab fragments are equine.
5	The antivenom pharmaceutical composition of claim 1, wherein the Fab fragments are obtained from hyperimmune serum.
6	The antivenom pharmaceutical composition of claim 1, wherein the Fab fragments are obtained from animal serum.
7	The antivenom pharmaceutical composition of claim 6, wherein the animal serum has been partially purified by ammonium sulfate precipitation.
8	The antivenom pharmaceutical composition of claim 1, further comprising $F(ab)_2$ fragments.
9	The antivenom pharmaceutical composition of claim 1, wherein the Fab fragments are obtained from polyvalent antibodies.
13	The antivenom pharmaceutical composition of claim 12, wherein the population of antibodies is raised to the venom of a snake of the *Crotalus* genus.
15	The antivenom pharmaceutical composition of claim 13, wherein the snake of the *Crotalus* genus is selected from the group consisting of *Crotalus adamanteus, Crotalus atrox,* and *Crotalus durissus.*
16	The antivenom pharmaceutical composition of claim 13, further comprising a population of antibodies raised to a venom of *Bothrops atrox.*
17	The antivenom pharmaceutical composition of claim 1, wherein the composition is in lyophilized form.
18	The antivenom pharmaceutical composition of claim 1, wherein the snakebite victim is a human.
19	An antivenom pharmaceutical composition for treating a human snakebite victim, comprising equine polyvalent Fab and $F(ab)_2$ fragments obtained from the serum of horses hyperimmunized with venom of at least one species of snake that belongs to the *Crotalus* genus, wherein the antivenom pharmaceutical composition binds to a venom of a snake of the *Crotalus* genus, wherein the antivenom pharmaceutical composition is essentially free from contaminating Fc, and a pharmaceutically acceptable carrier,

	wherein the antivenom pharmaceutical composition neutralizes the lethality of the venom of a snake of the *Crotalus* genus.
21	A method of treating envenomation by a snake of the *Crotalus* genus comprising administering the antivenom pharmaceutical composition of any one of claims 1-3, 4, 5-14, and 15-20.
22	The method of claim 21, wherein the antivenom pharmaceutical composition is administered intravenously.

5. Claims 1, 19, and 21 are independent claims. Claim charts for the independent claims are attached as Exhibit 3.

6. Respondents' activities with respect to the importation into the United States, the sale for importation into the United States, and/or the sale within the United States after importation of the Accused Products, as described more fully in Section V below, are unlawful under 19 U.S.C. § 1337(a)(1)(B)(i) in that they constitute the infringement of one or more valid and enforceable claims of the '414 patent and because a domestic industry, as required by 19 U.S.C. §§ 1337(a)(2) and (3) exists in the United States relating to the technology protected by the '414 patent.

7. BTG seeks a permanent limited exclusion order prohibiting Respondents from importing Accused Products, including but not limited to Antivipmyn, Anavip, an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*," and any other Fab-containing crotalid antivenom compositions that infringe one or more claims of the '414 patent and which are manufactured by or on behalf of, or imported by or on behalf of any Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns, from entry for consumption into the United States, entry for consumption from a foreign trade-zone, or withdrawal from a warehouse for consumption, for the remaining term of the '414 patent, except under license of BTG or as provided by law.

8. BTG further seeks the entry of permanent cease and desist orders, pursuant to 19 U.S.C. § 1337(f), directing Respondents and any of their principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) or majority-owned business entities, successors, and assigns, from either directly engaging in or for, with or otherwise on behalf of Respondents, (A) importing or selling for importation into the United States the Accused Products or other formulations that infringe one or more claims of the '414 patent; (B) marketing, distributing offering for sale (including via the Internet or electronic mail), selling or otherwise transferring, in the United States imported Accused Products or other formulations that infringe one or more claims of the '414 patent; (C) advertising in the United States imported Accused Products or substantially similar formulations prepared therefrom that infringe one or more claims of the '414 patent; (D) soliciting U.S. agents or distributors for Accused Products or other formulations that infringe one or more claims of the '414 patent; or (E) aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of Accused Products or other formulations in the United States that infringe one or more claims of the '414 patent.

9. BTG further seeks any other relief the Commission is authorized to grant and deems appropriate.

II. THE PARTIES

A. Complainant

10. BTG is a Delaware corporation having its principal place of business at Five Tower Bridge, Suite 800, 300 Barr Harbor Drive, West Conshohocken, Pennsylvania, 19428-2998, USA. BTG was incorporated in Delaware in June of 1990.

11. BTG is a growing international specialist healthcare company whose mission is to bring to market medical products that meet the needs of specialist health-care providers and their patients across the world. BTG manufactures and sells the product CroFab® Crotalidae Polyvalent Immune Fab (Ovine) ("CroFab®"), which is a pioneering antibody-based treatment for patients that have been bitten by North American crotalids, including rattlesnakes (Crotalus) and several other genera of poisonous snakes – a serious health threat that impacts victims in all forty-eight continental states. CroFab® antivenom is covered by the '414 patent and is presently the standard of care in the United States for treatment of envenomation (poisoning from a venomous bite or sting) by North American crotalids.

12. Thanks to the "availability of CroFab®," rattlesnake and other crotalid-related deaths in the United States have become "exceedingly rare" even though "several thousand" victims are bitten every year. See Exhibit 4; David Maurer, "Snakebite, Part 2: The journey of antivenin," The Daily Progress, Charlottesville, Va. (June 24, 2012).

13. The '414 patent claims valuable technology in the field of snake antivenom and marks a significant advance over prior methods for treating envenomation by North American crotalids. BTG owns, by assignment, the '414 patent, which is a valid and enforceable United States patent. Pursuant to Commission Rule 210(a)(9)(ii), certified copies of the recorded assignments are attached hereto as Exhibit 2.

14. BTG has invested significant resources in developing a domestic industry that advances the technology claimed in the '414 patent. Indeed, CroFab® is currently the only crotalid antivenom available in the United States and approved by the United States Food and Drug Administration ("FDA"). Confidential Exhibit 5, Declaration of Matthew Gantz ("Gantz Decl.") ¶ 11. CroFab® is FDA-approved for human use and is currently awaiting approval by

the United States Department of Agriculture ("USDA") for a veterinary indication as well. CroFab® used for medical purposes and CroFab® used for veterinary purposes (being developed under the name CroVet®) are chemically and pharmacologically identical.

15. CroFab® is used to treat crotalid bite victims and, more specifically, to halt the progression of various harmful symptoms, including the occurrence of systemic coagulation abnormalities that otherwise result from such envenomation. In January 1994, CroFab® (at the time known as CroTAb) was designated by the FDA as an orphan drug, meaning that it targeted a rare disease or condition (in this case, crotalid envenomation). Exhibit 6; January 12, 1994 Letter from Department of Health & Human Services.

B. Respondents

1. <u>Introduction</u>

16. There are seven Respondents in this action, all of which are related to one another by their activities in the development, manufacture, importation into the United States, sale and distribution of the Accused Products in the United States, as described more fully below. Several of the Respondents are related corporate entities. Respondent, Silanes Group, is the parent corporation of (and on information and belief, directs the activities of) Respondents Bioclon and Laboratorios Silanes. As described below, Bioclon and Laboratorios Silanes are Mexican entities that manufacture and import the Accused Products into the United States. Respondent Veteria Labs is a Mexican entity that handles sales and importation of the Accused Products into the United States for veterinary use. Respondent BioVeteria is a U.S. affiliate of Veteria Labs which facilitates the importation of the Accused Products into the United States and is involved in the application for approval of the Accused Product for veterinary use in the United States. Respondent RDT has partnered with Bioclon to develop and sell the Accused

Products in the United States and is the sponsor of the FDA application for approval for the Accused Products for human use in the United States and is the United States distributor for the Accused Products and will distribute the Accused Products in the United States once they have been approved. Accredo is also a United States distributor of the Accused Product and will distribute the Accused Products once they have been approved.

2. Veteria Labs

17. As discussed below in Section V, Veteria Labs has unlawfully imported the Accused Products into the United States. Veteria Labs currently imports (and did import to a United States veterinarian, as described more fully below) the Accused Products, and specifically a product labeled "Antivenin-*Bothrops asper* and *Crotalus durissus,*" from its facilities in Mexico into the United States. Veteria Labs also maintains a website which directs customers to take a series of specific actions in order to purchase, import into the United States, and obtain the accused Antivipmyn from Mexico

18. Veteria Labs is a corporation organized under the laws of Mexico, with its principal place of business at Lucerna # 7 Col. Juárez C.P. México D.F. 06600. Veteria Labs engages in the research, development, manufacture and/or distribution of an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*," and substantially similar products referred to by alternate trade names in Mexico for worldwide distribution including into the United States in conjunction with one or more of the other Respondents named in this Complaint.

19. Veteria Labs has maintained a website from which it provides information instructing customers how to import and order the Accused Products from Mexico. See Exhibit 7, http://veteria.com/veterinary-antivenoms-order-direct/ (screenshot of website captured as of

September 4, 2013). On information and belief, Veteria Labs, previously known as T.I. Salud S.A. de CV, was established to manage the ordering of the Accused Products by United States customers seeking to purchase the Accused Products from BioVeteria.

20. On information and belief, Veteria Labs is responsible, directly or indirectly, for at least Veteria Labs' infringing activities. Veteria Labs owns and/or controls operations in Mexico that manufacture, import into the United States, and/or distribute in the United States the Accused Products sold under brand names, including an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*," and other substantially similar compositions that infringe one or more claims of the '414 patent that Veteria Labs owns or licenses.

21. On information and belief, Juan Antonio Lopez de Silanes is the President of Veteria Labs.

3. <u>BioVeteria</u>

22. As discussed below in Section V, BioVeteria has unlawfully imported the Accused Products into the United States. BioVeteria imports, tests and distributes the Accused Products, including Antivipmyn and/or an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*" in the United States to veterinarians and other customers. For example, and as described more fully below, BioVeteria funded a study performed by Craig Woods, DVM, and described in the publication, Woods, et al. 2011, "Clinical safety evaluation of F(ab')2 antivenom (Crotalus durissus – Bothrops asper) administration in dogs" ("Woods 2011"). Exhibit 8. On information and belief, the F(ab')2 antivenom used by Woods and BioVeteria was Antivipmyn imported into the United States from Bioclon in Mexico.

23. BioVeteria is a limited liability company organized under the laws of the State of Arizona with its principal place of business at 1042 Willow Creek Road; Suite A101-482, Prescott, Arizona, 86301.

24. BioVeteria is the United States affiliate of Veteria Labs, and Juan Antonio Lopez de Silanes is the corporate manager and a member of this limited liability company.

25. BioVeteria was originally incorporated as Veteria Animal Health, LLC before changing its name to BioVeteria, and it maintains the website http://bioveteria.com/ (veteriaus.com). On information and belief, BioVeteria imports into the United States and/or distributes in the United States an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*," and other substantially similar compositions that infringe one or more claims of the '414 patent through a partnership with Veteria Labs. The "Store" tab at http://bioveteria.com/ links directly to Veteria Labs' website, as does the "Antivenoms" tab, from which a customer can access the instructions depicted in Exhibit 7.

26. On information and belief, BioVeteria is responsible, directly or indirectly, for at least BioVeteria's infringing activities. BioVeteria is a privately-held veterinary biopharmaceutical company which owns and/or controls laboratories, research facilities, and veterinary locations in Arizona that import into the United States and/or distribute in the United States the Accused Products sold under brand names, including an antivenom product labeled as "Antivenin-*Bothrops asper* and *Crotalus durissus*."

4. Bioclon

27. As discussed below in Section V, Bioclon has unlawfully imported the Accused Products into the United States. Bioclon manufactures the Accused Product in Mexico and imports it into the United States for, *inter alia,* research and marketing studies performed by its

United States affiliates, including BioVeteria. For example, Bioclon imported the F(ab')2 antivenom used by Woods and BioVeteria in the Woods 2011 study described above.

28. Bioclon is a corporation organized under the laws of Mexico with its principal place of business at Calzada de Tlalpan No. 4687, Col. Toriello Guerra, Tlalpan, Ciudad De Mexico, D.F. 14050. On information and belief, Bioclon engages in the research, development, and manufacture of Antivipmyn and Anavip and substantially similar products referred to by alternate trade names in Mexico for worldwide distribution including into the United States through one or more of the other Respondents named in this Complaint. Bioclon is responsible, directly or indirectly, for at least Bioclon's infringing activities.

29. Bioclon owns and/or controls manufacturing operations, including in Tlalpan, Ciudad De Mexico, Mexico that manufacture, import into the United States and/or distribute in the United States the Accused Products sold under brand names, including Antivipmyn and Anavip, that Bioclon owns or licenses. Exhibit 9 at 9.

30. Juan Antonio Lopez Silanes is the President of Bioclon and the Vice President of Research and Development of Laboratorios Silanes. Bioclon is a division of the Silanes Group.

31. On information and belief, Bioclon maintains at least one manufacturing plant at the above location in Mexico City and has imminent plans to open a second. According to information found at the www.silanes.com.mx website "half million bottles of anti-venom are produced a year [at the current Mexico City plant]; with the creation of the new plant it is estimated to increase six times that number to meet the global market." Exhibit 10 at 7 (screenshot captured as of June 28, 2013).

5. Laboratorios Silanes

32. As discussed below in Section V, Laboratorios Silanes has unlawfully imported the Accused Products into the United States. Laboratorios Silanes is a corporate affiliate of Bioclon, and on information and belief, is involved in the manufacture and importation of the Accused Products into the United States for marketing and sale.

33. Laboratorios Silanes is a corporation organized under the laws of Mexico with its principal place of business at Amores 1304, Col. Del. Valle, Mexico D.F., C.P. 03100. On information and belief, Laboratorios Silanes is a division of the Silanes Group. On information and belief, Laboratorios Silanes is a parent and/or affiliate company of Bioclon. Antonio Lopez Silanes is CEO of Laboratorios Silanes and Silanes Group. On information and belief, Laboratorios Silanes distributes Antivipmyn and Anavip, including importing the same into the United States. On information and belief, Laboratorios Silanes is responsible, directly or indirectly, for at least Laboratorios Silanes' infringing activities.

6. Silanes Group

34. As discussed below in Section V, Silanes Group has unlawfully imported the Accused Products into the United States. Silanes Group is a corporate parent of Bioclon, and on information and belief, is involved in directing and funding the manufacture and importation of the Accused Products into the United States for testing, marketing and sale.

35. Silanes Group is a corporation organized under the laws of Mexico with it principal place of business at Amores 1304, Col. Del. Valle, Mexico D.F., C.P. 03100. On information and belief, the Silanes Group is a national capital corporation with an international presence, to which Bioclon and Laboratorios Silanes belong. Exhibit 11 at 10-11 (screenshot

captured as of June 28, 2013). On further information and belief, Silanes Group is the parent corporation of both Laboratorios Silanes and Bioclon.

7. RDT

36. As discussed below in Section V, RDT, in partnership with Bioclon, has unlawfully imported the Accused Products into the United States. RDT is a known joint collaborator with Bioclon on the importation and distribution of the Accused Products in the United States. On information and belief, RDT is involved in distribution and sale of the imported Accused Products throughout the United States.

37. RDT is a corporation organized under the laws of the State of Tennessee with its principal place of business at 2550 Meridian Boulevard, Franklin, Tennessee 37067-63792. On information and belief, RDT is a United States distributor of Antivipmyn, Anavip, and/or other compositions that infringe one or more claims of the '414 patent and has signed a joint development and distribution agreement with Bioclon to distribute the same in the United States. See Exhibit 12 at 2. On information and belief, RDT is responsible, directly or indirectly, for at least RDT's infringing activities. On information and belief, RDT owns and/or controls research and development and distribution operations in Tennessee that import, and/or distribute in the United States the Accused Products sold under brand names, including Antivipmyn and Anavip.

8. Accredo

38. As discussed below in Section V, Accredo, in partnership with Bioclon, has unlawfully imported the Accused Products into the United States. On information and belief, Accredo is involved in distribution and sale of the imported Accused Products throughout the United States.

39. Accredo is a corporation organized under the laws of the State of Delaware with its principal place of business located at 1640 Century Center Parkway, Memphis, Tennessee 381343. On information and belief, Accredo is a specialty pharmaceutical distributor that operates a pharmacy and provides related services for patients with complex or rare conditions. See Exhibit 13 (screenshot captured as of June 28, 2013). On information and belief, Accredo intends to distribute in the United States Antivipmyn, Anavip, or other compositions that infringe one or more claims of the '414 patent. On information and belief, Accredo is responsible, directly or indirectly, for at least Accredo's infringing activities.

III. THE TECHNOLOGY AND PRODUCTS AT ISSUE

A. The Technology

40. The '414 patent relates generally to a pharmaceutical composition and corresponding method for treating snakebite victims where the pharmaceutical composition includes a particular type of antibody fragments, known as "Fab" fragments.[2] For example, the technology described and claimed in the '414 patent is utilized to create purified antivenom of the type marketed in the United States as CroFab® and sold by BTG.

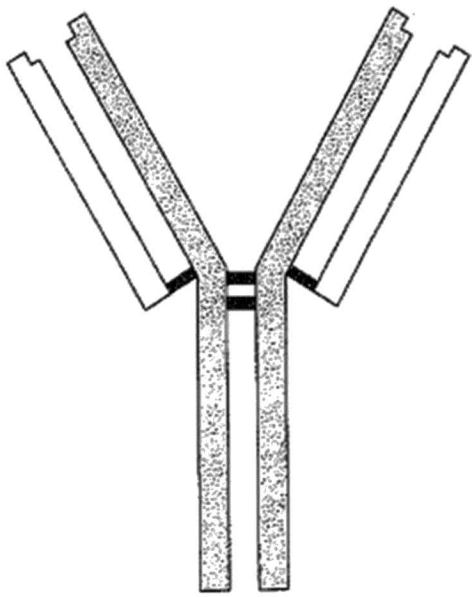
41. Prior to the filing of the '414 patent, researchers had long known that the most effective response to a rattlesnake bite is to administer antivenom – a suspension of venom-neutralizing antibodies harvested from animals (traditionally horses) that had been exposed to increasing doses of the toxins. Such antivenoms suffered from critical drawbacks, most prominently they tended to elicit "serum sickness," a potentially life-threatening immune reaction to immunoglobulin molecules. Until the '414 patent inventors developed the invention

[2] The text of this Complaint is not intended to interpret the meaning or limit the scope of the claims of the '414 patent.

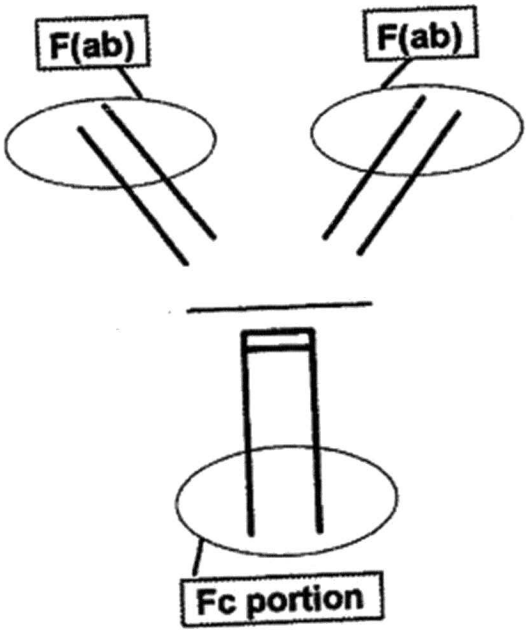
described therein, the only rattlesnake antivenom commercially available in the United States – Wyeth's Antivenom (Crotalidae) Polyvalent ("ACP") – triggered serum sickness in many cases.

42. ACP consists of whole Immunoglobulin G ("IgG") antibodies harvested from animals exposed to snake venom. By contrast, the antivenom pharmaceutical compositions covered by the '414 patent inventors include a particular type of immunoglobulin fragment.

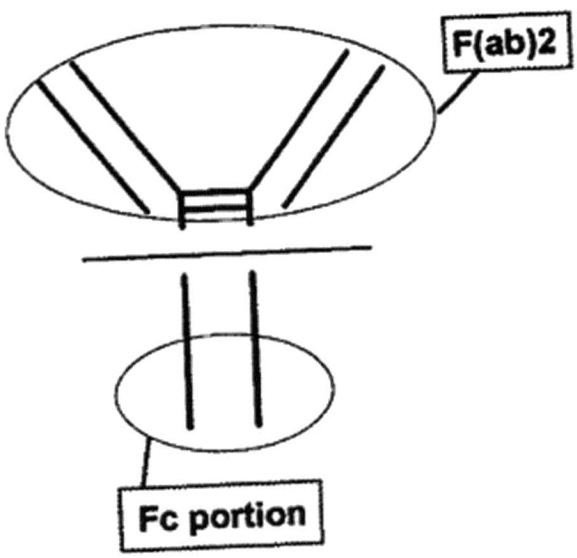
43. Whole IgG molecules are shaped like a "Y":



44. Each upper arm of the Y contains an active site for binding antigens like the toxins in rattlesnake venom. Combining IgG molecules with one type of enzyme separates the two arms from one another and also breaks them apart from the stem of the molecule. The result is two separate "Fab fragments" (i.e., the two upper arms of the Y, each with an active site) as well as an "Fc fragment" (i.e., the stump that remains):



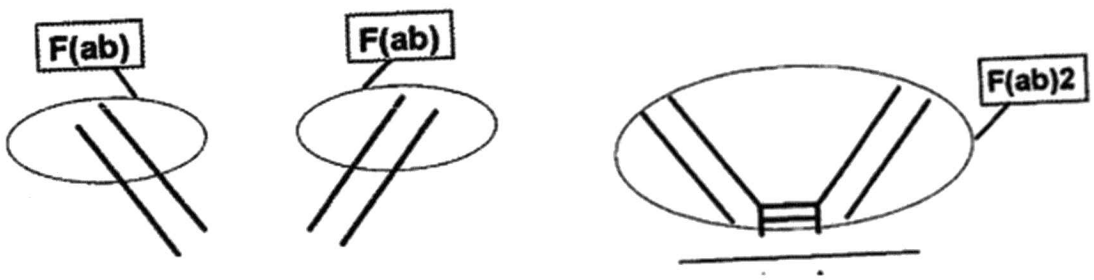
By contrast, combining IgG with a different kind of enzyme cleaves the upper arms off the stem but keeps them attached to each other. This affords a single "$F(ab')_2$" fragment as well as an Fc stump:



45. The invention described in the '414 patent relates to antibody compositions and related methods of use. The claimed composition includes Fab fragments and is essentially free from Fc fragments.

46. Fab fragments had long been known to have potential application as an antidote for certain individual toxic compounds, dating back at least to the use of Fab fragments to treat digoxin overdose in 1971.

47. Furthermore, various antivenoms that eliminated the Fc fragment had been made and used. Those antivenoms, however, comprised $F(ab')_2$ fragments, not Fab fragments. $F(ab')_2$ fragments differ from Fab fragments by being split from the Fc portion below the "hinge" rather than above the hinge, as described above. The result is that $F(ab')_2$ fragments comprise two antigen binding sites, still joined at the hinge, while Fab fragments split into two separate binding sites:



48. Despite the relatively widespread use of antivenoms comprising $F(ab')_2$ fragments as well as the use of Fab fragments against certain individual toxins (as opposed to snake venom itself), no one prior to the '414 patent inventors had attempted to develop an antivenom comprising Fab fragments.

49. Although there were widespread concerns regarding the viability of antivenoms that included Fab fragments, the inventors prepared an antivenom with Fab fragments and tested

its ability to neutralize the lethality of rattlesnake venom. Unexpectedly, they found that the antivenom with Fab fragments not only neutralized the lethality of rattlesnake venom, but did so better than the existing ACP product, and even IgG purified from ACP. These results are reflected in the specification of the '414 patent itself.

50. Later clinical testing confirmed that CroFab®, the commercial embodiment of the claimed invention, was significantly more potent than ACP.

B. The Accused Products

51. The Accused Products are antivenoms for the treatment of envenomation by North American crotalids (e.g., rattlesnake bites). On present information and belief, known commercial names for the Accused Products include Antivipmyn and Anavip and an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*," but the scope of the Accused Products extends to all compositions that are covered by one or more claims of the '414 patent and have been imported, marketed, and/or sold by the Respondents in the United States, including products generically labeled as "Antivenin-*Bothrops asper* and *Crotalus durissus.*"

52. The Accused Products have been imported, without authorization, into the United States for use by veterinarians, health care professionals, zoos and others. By way of example and as described more fully below, U.S. Veterinarian Dr. Jennifer Hummel ordered 15 vials of the Accused Product from Veteria Labs in Mexico and the Accused Product was imported into the United States by Veteria Labs (in partnership with Respondent BioVeteria) from Mexico and sent to Dr. Hummel's location in the United States.

53. In addition to the importation of the Accused Product to Dr. Hummel, Bioclon indicates that its product Antivipmyn is intended for use in Mexico and the United States. See Exhibit 14 (screen shot captured as of June 28, 2013). On information and belief, Bioclon is

importing this product into the United States for marketing and market seeding activities in the hopes that it will be able to capture significant market share once the Accused Product is approved for human use.

54. Bioclon has indicated that it has conducted, under FDA BB IND 11,275, clinical studies for entering new markets, seeking approval for use in the United States of an "anti-snake" antivenom. See Exhibit 15 (screen shot captured as of June 28, 2013). On information and belief, Bioclon has also told the FDA that Antivipmyn is also known as Anavip and that Bioclon has conducted clinical studies for the treatment of pit viper envenomation. Exhibit 9 at 12-13. The Spanish language version of Bioclon's website describing the clinical studies for entering new markets for an antivenom in the United States uses the name "Anavip," (see Exhibit 16 (screen shot captured as of June 28, 2013)) even though other parts of the Spanish language website use the name Antivipmyn for the antivenom for the United States. See Exhibit 17 (screen shot captured as of June 28, 2013).

55. On information and belief, the Accused Products being imported, distributed and sold by the Respondents constitute pharmaceutical compositions comprising Fab fragments and which are essentially free from Fc.

56. Because the information regarding the Accused Products in this Complaint is based upon BTG's present knowledge and understanding, BTG reserves the right to add additional Accused Products should such be identified through the course of discovery.

IV. THE PATENT AT ISSUE

A. The '414 Patent (U.S. Patent No. 8,048,414)

1. Identification of the Patent Ownership by BTG

57. BTG owns by assignment the entire right, title and interest in the '414 patent entitled, "Antivenom Composition Containing Fab Fragments," which issued on November 1, 2011. The '414 patent issued to inventors John B. Sullivan and Findlay E. Russell from United States Patent Application No. 08/405,454, filed on March 15, 1995, and descending via a number of continuations from United States Patent Application No. 06/659,629 ("the '629 application"). It expires on November 1, 2028.

58. Pursuant to Commission Rule 210.12(c), a certified copy and three additional copies of the prosecution history of the '414 patent are attached as Appendix A. Four copies of each patent and applicable pages of each technical reference mentioned in the prosecution history of the '414 patent are attached as Appendix B.

2. Non-Technical Description of the '414 Patent

59. Pursuant to Commission Rule 210.12(a)(9)(vi), BTG provides the following non-technical description of the invention of the '414 patent.

60. The '414 patent has 22 claims: 3 independent claims and 19 dependent claims.

61. As noted above, the '414 patent generally relates to compositions for treating snakebite victims and methods for using the same. It also describes methods for purifying the necessary antibodies utilizing affinity chromatography processes. See Exhibit 1. The '414 patent inventors pioneered the use of pharmaceutical formulations that include Fab fragments to neutralize crotalid venom safely and reliably.

62. By contrast, prior art antivenom products, comprising either IgG or $F(ab')_2$ fragments, were only modestly effective and frequently invoked adverse immune reactions in humans. As discussed above, despite the shortcomings of previous treatments, researchers prior to the '414 patents' inventors did not experiment with Fab-based antivenoms.

63. Surprisingly, however, the inventors' results were the opposite from what conventional wisdom suggested. They discovered that Fab fragments are effective at neutralizing the lethality of rattlesnake venom, while reducing the occurrence of adverse immune reactions in humans.

64. The '414 patent therefore claims pharmaceutical compositions for treating snakebite victims which comprises Fab fragments and which are essentially free from contaminating Fc fragments.

3. Foreign Counterparts to the '414 Patent

65. Pursuant to Commission Rule 210.12(a)(9)(v), no foreign patents or patent applications related to the '414 patent have been filed, granted, abandoned, withdrawn, or rejected.

4. Additional Litigation Involving the '414 Patent

66. Pursuant to Commission Rule 210.12(a)(5), Complainant states that the unfair acts described in this Complaint are not and have not been the subject of any court or agency litigation. Complainant further states that the '414 patent is not currently involved in any other court or agency litigation. The '414 patent was involved in an appeal to the United States Court of Appeals for the Federal Circuit which was an appeal from a final rejection of the claims of the '414 patent by an examiner of the United States Patent and Trademark Office. That appeal was In re John B. Sullivan and Findlay F. Russell, 498 F.3d 1345 (Fed. Cir. 2007).

B. Licensees Under the '414 Patent

67. Pursuant to Commission Rule 210.12(a)(9)(iii), BTG states that there are, at present, no licensees under the '414 patent.

68. Pursuant to Commission Rule 210.12(a)(9)(iv), BTG states that it is not relying upon its licenses to the '414 patent to support its contention that a domestic industry as defined in Section 337(a)(3) exists.

V. SPECIFIC INSTANCES OF IMPORTATION AND SALE

69. On information and belief, one or more Respondents manufacture the Accused Products in Mexico.

70. On information and belief, one or more of the Respondents, directly or through agents acting on their behalf, manufacture, import into the United States, sell or offer for sale for importation into the United States, and/or sell within the United States after importation the Accused Products. Pursuant to Commission Rule 210.12(a)(3), the specific instances of importation of the Accused Products set forth below are examples of the unlawful importation and/or sale after importation of infringing articles.

A. Summary of Respondents' Unlawful Importation and Sale

71. The Accused Product has been unlawfully imported from Mexico into the United States and has been sold to various individuals, including veterinarians and other health care professionals for their use in treating snakebites in the United States. By way of example, and as detailed more fully below, U.S. Veterinarian Dr. Jennifer Hummel ordered 15 vials of the Accused Product from Respondents in Mexico and the Accused Product was sent by Respondents to Dr. Hummel's location in the United States. See Exhibit 18, Declaration of Dr. Jennifer Hummel ("Hummel Decl."). Respondents provide information (via their websites)

about how to order and import the Accused Product to United States veterinarians interested in purchasing the Accused Product from Mexico. Dr. Hummel is aware of other instances of the same importation by Respondents of the Accused Products to other veterinarians in the United States.

72. In addition to Respondents' importation of the Accused Product to veterinarians in the United States, Respondents have imported the Accused Product into the United States for purposes of marketing and market seeding activities, in anticipation of FDA approval of the Accused Product in the United States for human use.

73. The Accused Product is currently undergoing clinical trials for approval to market and sell the Accused Product for treatment of humans and Complainant fully expects Respondents to begin commercial sale and further unlawful importation of the Accused Product in the United States immediately upon securing such approval.

74. Below are the specific instances in which each Respondent has been involved in the above-summarized unlawful acts.

B. Specific Instances of Veteria Labs' Unlawful Importation and Sale

75. U.S. Veterinarian Dr. Jennifer Hummel ordered 15 vials of the Accused Product from Veteria Labs and this Accused Product was imported into the United States by Veteria Labs (in partnership with another Respondent BioVeteria) from Mexico and sent to Dr. Hummel's location in the United States. See Exhibit 18, Declaration of Dr. Jennifer Hummel.

76. Veteria Labs currently imports (and did import to Dr. Hummel) the Accused Products, and specifically a product labeled "Antivenin- *Bothrops asper* and *Crotalus durissus,*" from its facilities in Mexico into the United States.

77. Veteria Labs maintains a website, accessible through the BioVeteria website which directs customers to take the following actions to purchase and obtain the accused Antivipmyn from Mexico:

a. Veteria Labs instructs that in order to obtain the Accused Product, an Import Permit from the USDA is required. See Exhibit 7.

b. Veteria Labs provides instructions on how to apply for such a permit. See Exhibit 7.

c. Veteria Labs instructs that if a permit is already in the customer's possession or a permit has been secured, a customer should contact Veteria Labs directly via e-mail or phone to place an order. See Exhibit 7.

d. Finally Veteria Labs provides information on how the product will travel into the United States, including the possibility of it being held by U.S. Customs. See Exhibit 7.

78. Dr. Hummel contacted Veteria Labs (then operating under its former name "T.I. Salud") on February 10, 2013. Exhibit 18, Hummel Decl., ¶¶ 4-6.

79. Per the instructions provided to her by Veteria Labs, on February 11, 2013, Dr. Hummel filed an import permit application with the USDA Animal and Plant Health Inspection Service. She completed and submitted that application to the USDA on February 11, 2013. Exhibit 18, Hummel Decl., ¶¶ 7-8.

80. Dr. Hummel received her granted permit on February 14, 2013 and on February 20, 2013, she contacted Veteria Labs to order 15 vials of the Accused Product. Exhibit 18, Hummel Decl., ¶¶ 9-10.

81. On February 28, 2013, Dr. Hummel received an e-mail from Diana Varea (via e-mail address dvarea@tisalud.com.mx) with further instructions and a list of requisite information for ordering the Accused Products. Dr. Hummel provided the requested information by e-mail on the same day. Exhibit 18, Hummel Decl., ¶¶ 12-13. Ms. Varea is presently listed as the contact for Veteria Labs on their web site, listing an Arizona phone number. See Exhibit 19 (screenshot captured as of September 11, 2013).

82. On March 4, 2013, Ms. Varea informed Dr. Hummel that she had charged Dr. Hummel's credit card and processed her order for the Accused Products. Exhibit 18, Hummel Decl., ¶¶ 14-15.

83. On March 12, 2013, Dr. Hummel learned that her order had reached United States Customs. She reported this information to Ms. Varea on the same day. Exhibit 18, Hummel Decl., ¶ 16.

84. Ms. Varea responded to Dr. Hummel and referred her to Dr. Craig Woods at BioVeteria in the United States who was to assist Dr. Hummel in working to release the shipment from Customs. Exhibit 18, Hummel Decl., ¶ 17.

85. Dr. Hummel worked with Dr. Woods at BioVeteria and completed and sent the necessary paperwork for releasing her order from Customs on March 13, 2013. Exhibit 18, Hummel Decl., ¶ 18.

86. On March 30, Dr. Hummel received her order of the Accused Products with invoices indicating that the "Sender name" was Veteria Labs. Exhibit 18, Hummel Decl., ¶ 19. Dr. Hummel was charged $4,875.20 ($221.60 per vial) for her order of the Accused Products from Mexico. Exhibit 18, Hummel Decl., ¶ 19.

87. The Accused Products received were labeled "Antivenin- *Bothrops asper* and *Crotalus durissus*." Their labeling indicates that they were manufactured by: Veteria Labs S.A. de C.V. R.F.C VLA950601LJ7; Lucerna #7 Colonia Juarez, C.P. 06600 Mexico. Exhibit 18, Hummel Decl., ¶ 19. The Accused Products were accompanied by a letter from Juan Antonio Lopez Silanes de Blanco, the CEO of Veteria Laboratories, and, on information and belief, the corporate manager and a company member of Respondent BioVeteria.

88. Dr. Hummel's purchase invoice indicates that her credit card was charged by T.I. Salud Mexico DF. On information and belief, T.I. Salud is the previous name (or predecessor) to Veteria Labs. As of July 5, 2012 the website http://vetantivenom.com linked to T.I. Salud's website (also located at this website http://tisalud.com.mx/indExhibithtml). Currently, http://vetantivenom.com links to Veteria Labs' website. As of July 5, 2012, however, T.I. Salud's website contained ordering instructions for Antivipmyn. T.I. Salud's website stated the following:

> Section 4: Instituto BioClon; S.A. de C.V. 2008. Calzada de Tlalpan # 4687, Col. Toriello
> Guerra. C.P. 14050, México D.F
> Section 5: ***Antivipmyn*** – F(ab')2 pit viper antivenom
> Section 6: date you expect to receive your shipment.
> Section 7: # vials you expect to use during one year.
> Section 8: your State
> Section 9: We recommend the following language be used: "Institution Same as Section 3: Sterile fill polyclonal antivenom F(ab)2 antibody fragments from hyperimmunized horses against Crotalus durissus and Bothrops asper supplied as lyophilized solid in a 20mL injection vial. Purity: F(ab')2 is NLT 85%; Fab: NMT 2%; low molecular weight protein NMT 13%; IgG 5%. Immunoglobulins are purified by precipitation with ammonium sulfate and acidic pH. After filtration the IgG solution undergoes diafiltration formulation and sterilization. The antibodies are cleaved by pepsin to form F(ab')2 fragments which then undergo micron filtration to remove viruses. Product will administered intravenously in dogs and cats naturally envenomated by pit vipers."

See Exhibit 20 (screen shot captured as of July 5, 2012).

89. Veteria Labs' website currently contains the following, almost identical, information but instructs customers to indicate that the Producer is "Veteria Labs" rather than "Instituto BioClon." It also names the product "Antivenin– Bothrops asper & Crotalus durissus" rather than "Antivipmyn – $F(ab')_2$ pit viper antivenom," but substantively describes it as being the same product:

> On the next page, skip down and fill out the Producer's Information as follows:
> Organization: Veteria Labs S.A. de C.V.
> Street: Lucerna #7
> City: Mexico City
> Country: Mexico
> Zip: 06600
> On the next page, fill out the Product Shipment Section as follows (cut and past from here if necessary).
> Name of Product: Other
> Describe: Antivenin – Bothrops asper & Crotalus durissus
> Estimated Quantity: we advise putting in the number of vials you expect over 1 year
> Product Description: 20mL vial containing sterile, lyophilized antivenom F(ab')2 antibody fragments from horses hyperimmunized against Crotalus durissus and Bothrops asper. Immunoglobulins are purified by ammonium sulfate precipitation and subjected to diafiltration, nanofiltration, and sterile filtration to remove microorganisms. Product will be administered intravenously and evaluated in dogs and cats naturally envenomated by pit vipers.
>
> See Exhibit 7.

Indeed, the Veteria Labs website previously indicated that the individuals running Veteria Labs were involved with providing "Antivenin– Bothrops asper & Crotalus durissus" to the United States for 5 years and that T.I. Salud had simply transferred the ordering process directly to the new company. The website has subsequently been changed but used to state:

> Q: I have never done business in Mexico, who am I dealing with here?
> A: Veteria Labs S.A. de C.V. is a group of professionals that have been associated with antivenom development for decades. Although Veteria Labs is our new company, our personnel have been working with US veterinarians for over 5 years in providing high quality F(ab')2 antivenoms. This includes Veterinary Teaching Hospitals, specialty clinics, and general practices. Our distributor (tiSALUD) is now transitioning the ordering process directly to Veteria Labs (us, the manufacturer).

90. At a minimum, the above evidence demonstrates that Veteria Labs is responsible for importing the Accused Products into the United States from Mexico.

C. Specific Instances of BioVeteria's Unlawful Importation and Sale

91. On information and belief, and as only one example, BioVeteria imports, tests and distributes the Accused Products, including Antivipmyn and/or an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*" in the United States to veterinarians and other customers.

92. BioVeteria, located in the United States, collaborates with Veteria Labs, located in Mexico, to unlawfully import the Accused Product into this country. By way of example, the BioVeteria website (http://bioveteria.com/) utilizes a "STORE" tab, as well as an "Antivenoms" tab, to link customers from BioVeteria's website to Veteria Labs' website. As described above in paragraphs 75-88, Veteria Labs, in conjunction with BioVeteria, imported the Accused Products to Dr. Jennifer Hummel (who contacted Veteria Labs through its website) in the United States, from Mexico.

93. On information and belief, the "$F(ab')_2$ antivenom" imported by Dr. Hummel is Antivipmyn and/or an antivenom product labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus,*" and, as admitted, BioVeteria is facilitating the import of this product to the United States, from Mexico. BioVeteria's website directs U.S. veterinarians (like Dr. Hummel) to order from Veteria Labs S.A. de C.V.: "US Veterinarians: BioVeteria Life Sciences, LLC is not distributing or selling the veterinary antivenoms in the United States until we are issued a Permit for Distribution and Sale. Foreign antivenoms for veterinary use require appropriate import permits. More information can be found at the following links: Antivenom Producer: visit

Veteria Labs S.A. de C.V.-click here." See Exhibit 21 (screen shot captured as of September 4, 2013).

94. A prior version of BioVeteria's website contained a product page listing for "Crotalid Antivenom- F(ab')$_2$ Antivenom." This is further described on BioVeteria's website as "Antivenin– Bothrops asper and Crotalus durissus [USDA Product Code 6101.02, unlicensed]." The "Studies" tab on this webpage lists a number of publications of recent antivenom studies using F(ab')$_2$ Antivenin– Bothrops asper and Crotalus durissus. See Exhibit 22 (screen shot captured as of October 16, 2012). One such listed publication is Woods, et al. 2011, "Clinical safety evaluation of F(ab')$_2$ antivenom (*Crotalus durissus – Bothrops asper*) administration in dogs" ("Woods 2011"). See Exhibit 8.

95. On information and belief, the executive officers of BioVeteria are Juan Lopez De Silanes Perez, Member; Beatriz Lopez De Silanes Blanco, Member; and Juan Antonio Lopez De Silanes, Manager and Member.

96. On information and belief, Craig Woods DVM was a paid consultant to BioVeteria at the time the data for the Woods 2011 study was collected. See Exhibit 23 (screen shot captured as of July 8, 2013).

97. On information and belief, the Woods 2011 study was funded by BioVeteria.

98. On information and belief, the antivenom utilized in the Woods 2011 study was a polyvalent F(ab')$_2$ antivenom of equine origin.

99. Further, on information and belief, the F(ab')$_2$ antivenom used by Woods and BioVeteria was Antivipmyn from Bioclon. The Woods 2011 article states: "This study protocol was approved by the Institutional Animal Care and Use Committee at the research facility" and refers to the following additional information in a footnote: "Polyvalent F(ab)$_2$ pit viper

antivenom [Crotalus durissus and Bothrops asper]. Instituto Bioclon S.A. de C.V. 2011, Terminos de uso. Calzada de Tlalpan # 4687, Col. Toriello Guerra. C.P. 14050, Mexico D.F." See Exhibit 8.

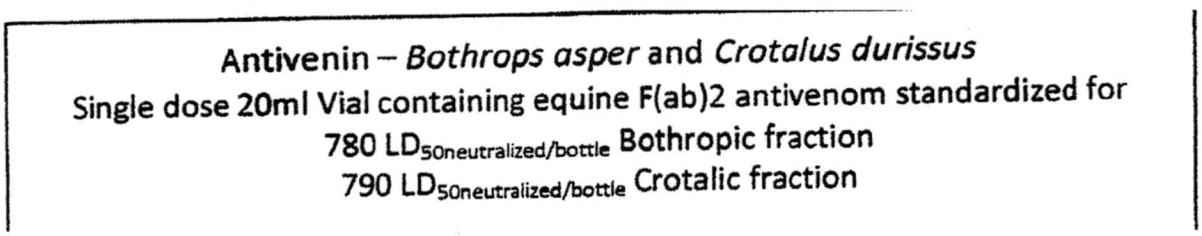
100. The description of the product studied in the Woods 2011 article, including the potency, are identical to the documents describing the product imported to Jennifer Hummel DVM, as described above. The Woods 2011 article states:

> "The antivenom used in this study was a polyvalent $F(ab)_2$ antivenom of equine origin. (b) $F(ab)_2$ antivenom was derived from a qualified herd of horses hyperimmunized against the venoms of Crotalus durissus and Bothrops asper and supplied as a lyophilized, white-pale to yellow porous solid in a 20 mL labeled injection vial containing specific equine-derived binding fragments. The minimum purity of $F(ab)_2$ antivenom used for release into the study contained no IgG (0%) and not more than 2% Fab fragments. The minimum potency of $F(ab)_2$ fractions were **Bothrops asper 780 DL50 neutralized** and **Crotalus durissus 790 DL50 neutralized**. Three lots were used in the study, being lots P-6B-05, P-7D-01, and B-8D-21 with an averaged crotalid fraction of 1088 DL50."

Exhibit 8 (emphasis added).

101. The description provided with the product imported by Dr. Hummel is,

Antivenin– *Bothrops asper* and *Crotalus durissus*
Description: the product is a polyclonal antivenom F(ab)2 fragment derived from a qualified herd of horses hyperimmunized against the venoms of Crotalus durissus and Bothrops asper. The product is supplied as a lyophilized, white-pale to yellow porous solid in a 20mL labeled injection vial containing specific equine derived binding fragments which are cross protective against numerous crotalid venoms. After reconstitution with 0.9% isotonic saline it appears as an opalescent slightly yellow liquid with a pH range of 6-7.



See Exhibit 24.

102. On information and belief, the product imported to Dr. Hummel and labeled "Antivenin- *Bothrops asper and Crotauls durissus"* as described above is substantially similar in

all material respects, including potency, presence of Fab fragments and method of manufacture, as the Antivipmyn product referenced in the Woods 2011 article, and the Antivipmyn and Anavip products described on Bioclon's website (discussed below).

103. On further information and belief, Craig W. Woods, DVM was the registrant for the domain name www.antivipmyn.com, until June 20, 2013 at which point Juan Antonio Silanes Blanco (the President of Veteria Labs) became the named registrant. See Exhibit 25 (screen shot captured as of September 4, 2013). The website associated with www.antivipmyn.com is presently undeveloped.

104. Furthermore, BioVeteria's website describes its Crotalid Antivenom- $F(ab')_2$ Antivenom as "[a] polyvalent snake antivenom consist[ing] of $F(ab')_2$ fragments derived from horses hyperimmunized against the snake venoms of Crotalus sp. and Bothrops sp. and shown to cross react (neutralize) venoms from all common North American pit vipers (rattlesnakes, copperheads, moccasins) (Sanchez, EE et. al. 2005)." Exhibit 22.

105. On information and belief, the citation on BioVeteria's web page contains a typo and refers instead to a Sanchez, EE et al. 2003 study. The Sanchez 2003 article cited specifically describes the studied product as follows:

> In this study, we tested two antivenoms. The first was a Crotalidae Polyvalent Fab fragment with Ovine origin (FabO) manufactured in London, and the second was Antivipmyn, a Mexican manufactured antivenom that is $F(ab')_2$ fragment produced in horse (Fab_2H). Antivipmyn (Fab_2H) is a polyclonal antivenom $F(ab')_2$ fragment of equine origin produced by Instituto Bioclon in Mexico. The venoms used to produce the Fab_2H were that of Crotalus durissus and Bothrops asper.

Exhibit 26, Abstract.

106. The Woods 2011 article indicates that the antivenom utilized in its study is the same product utilized in the Sanchez 2003 study. The Woods 2011 article states, "The polyvalent $F(ab)_2$ pit viper antivenom used in this study cross-protects against all common North

American pit viper venoms and has been previously assessed for canine safety under field conditions…Sanchez EE, Ramirez MS, Gal'an JA, et al. Cross reactivity of three antivenoms against North American snake venoms. Toxicon 2003; 41:315–320." Exhibit 8 at 565.

107. Furthermore, on information and belief, BioVeteria exhibited in the United States at the American Animal Hospital Association's 2013 conference in Phoenix, Arizona (Booth #840) where, on information and belief, it provided marketing updates about its Accused Product and that product's development and pathway to USDA approval. See Exhibit 27 at 2 (screen shot captured as of July 19, 2013). Such marketing supports BTG's allegation of imminent infringement by both Bioclon and BioVeteria.

108. Additionally, the Southern Arizona Veterinary Specialty & Emergency Center, located in Tucson, Arizona, describes research studies conducted and available at the Center, including the "efficacy and safety of Antivipmyn in Feline Rattlesnake Bite Patients." Exhibit 28 (screen shot captured as of July 19, 2013). This project is described as follows:

e. Study pays for the antivenom for these patients provided they have been envenomated within the last six hours.

f. Previously available antivenom products have been associated with serious, sometimes fatal anaphylaxis reactions. The study looks to demonstrate that this product will be well tolerated by the feline patients, as well as be effective.

g. ***Antivipmyn is provided by bioVeteria.***

Exhibit 28 at 2-3 (emphasis added).

109. Finally, on information and belief, BioVeteria has sought approval from the United States Department of Agriculture for importation of the Accused Products from Mexico

into the United States. For example, BioVeteria reports on its website under the heading "Crotalid Antivenom – $F(ab')_2$ Antivenom", that "This antivenom product is not yet approved in the United States. Veterinarians must obtain the appropriate import permits and should comply with any state and federal regulations associated with antivenom imports. BioVeteria does not sell this antivenom in the United States, but is working towards the approval." See Exhibit 29 (screen shot captured as of September 4, 2013).

110. At least the above evidence demonstrates that BioVeteria is responsible for unlawfully importing the Accused Products into the United States from Mexico.

D. Specific Instances of Bioclon's Unlawful Importation and Sale

111. Antivipmyn and/or Anavip are examples of Accused Products. On information and belief, Antivipmyn and/or Anavip are manufactured in Mexico by Respondent Bioclon. On information and belief, Bioclon manufactures the Accused Products in Mexico and facilitates its importation into the United States directly and through one or more of the other Respondents.

112. For example, as described above, Dr. Jennifer Hummel, a United States veterinarian, purchased 15 vials of a product that is the same or substantially similar to Antivipmyn, labeled as "Antivenin- *Bothrops asper* and *Crotalus durissus*". See Exhibit 18, Hummel Decl., ¶¶ 6-19. These vials were shipped to her in the United States from Mexico as depicted in the accompanying invoice. See Exhibit 18, Hummel Decl., ¶ 15 and Exhibit H3 to Hummel Decl.

113. On information and belief, this Accused Product is manufactured in Mexico by or at the direction of Bioclon in concert with Veteria Labs and/or BioVeteria and is imported into the United States.

114. On information and belief, Bioclon is the manufacturer and provider of the Accused Products sold by Respondents BioVeteria and RDT in the United States.

115. For example, and as stated above, BioVeteria's website contains a product page listing for "Crotalid Antivenom-F(ab')$_2$ Antivenin." This is further described on BioVeteria's website as Antivenin – Bothrops asper and Crotalus durissus [USDA Product Code 6101.02, unlicensed]. BioVeteria's website also cites to the Woods 2011 study. Exhibit 22.

116. As stated above, the Woods 2011 study was funded by BioVeteria and the antivenom utilized in the Woods 2011 study was a polyvalent F(ab')$_2$ antivenom of equine origin. Exhibit 8.

117. Further, on information and belief, the F(ab')$_2$ antivenom used and imported by BioVeteria and Woods was Antivipmyn from Bioclon. The Woods 2011 article states: "This study protocol was approved by the Institutional Animal Care and Use Committee at the research facility" and refers to the following additional information in a footnote: "Polyvalent F(ab')$_2$ pit viper antivenom [Crotalus durissus and Bothrops asper]. Instituto Bioclon S.A. de C.V. 2011, Terminos de uso. Calzada de Tlalpan # 4687, Col. Toriello Guerra. C.P. 14050, Mexico D.F." See Exhibit 8.

118. The description of the product studied in the Woods 2011 article, including the potency, are identical to the documents describing the product imported into the United States and sent to Dr. Jennifer Hummel, as described above. The Woods 2011 article states:

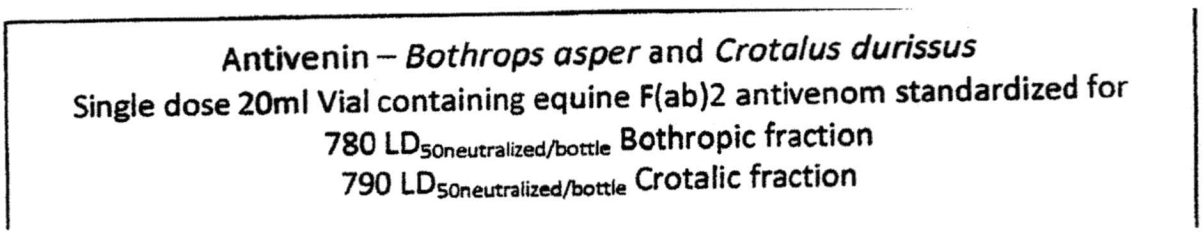
> "The antivenom used in this study was a polyvalent F(ab')2 antivenom of equine origin. (b) F(ab')$_2$ antivenom was derived from a qualified herd of horses hyperimmunized against the venoms of Crotalus durissus and Bothrops asper and supplied as a lyophilized, white-pale to yellow porous solid in a 20 mL labeled injection vial containing specific equine-derived binding fragments. The minimum purity of F(ab')$_2$ antivenom used for release into the study contained no IgG (0%) and not more than **2% Fab fragments**. The minimum potency of F(ab')$_2$ fractions were Bothrops asper 780 DL50 neutralized and

Crotalus durissus 790 DL50 neutralized. Three lots were used in the study, being lots P-6B-05, P-7D-01, and B-8D-21 with an averaged crotalid fraction of 1088 DL50."

Exhibit 8 at 566 (emphasis added).

119. The description provided with the product imported by Dr. Hummel is,

Antivenin– *Bothrops asper* and *Crotalus durissus*
Description: the product is a polyclonal antivenom F(ab)2 fragment derived from a qualified herd of horses hyperimmunized against the venoms of Crotalus durissus and Bothrops asper. The product is supplied as a lyophilized, white-pale to yellow porous solid in a 20mL labeled injection vial containing specific equine derived binding fragments which are cross protective against numerous crotalid venoms. After reconstitution with 0.9% isotonic saline it appears as an opalescent slightly yellow liquid with a pH range of 6-7.



See Exhibit 24.

120. On information and belief, the product imported to Dr. Hummel and labeled "Antivenin- *Bothrops asper and Crotauls durissus"* as described above is substantially similar in all material respects, including potency, presence of Fab fragments and method of manufacture, as the Antivipmyn product referenced in the Woods 2011 article, and the Antivipmyn and Anavip products described on Bioclon's website. See e.g., Exhibit 30 at 5, http://www.medicamentosplm.com/productos/antivipmyn_solucion_inyectable.htm (screenshot captured as of September 23, 2013, describing dosage standardizations as 780 LD50 and 790 LD50 for the Bothropic and Crotalic fractions, respectively).

121. On further information and belief, the executive officers of Bioclon include President Juan Lopez de Silanes, the son of Antoino Lopez di Silanes. On further information and belief, Bioclon funds a center for antivenom research named "Beatriz Lopez de Silanes Blanco" at la Universidad Nacional Autonoma de Mexico (UNAM). Exhibit 31 (screen shot

captured as of July 19, 2013). Beatriz Lopez de Silanes Blanco is one of BioVeteria's members. See Exhibit 32.

122. As noted above, Juan Lopez De Silanes is also an executive of BioVeteria. See ¶ 95 *supra*.

123. Furthermore, on information and belief, Bioclon completed a phase III study of Anavip in January 2012, and Bioclon and RDT have announced that they plan to sell Antivipmyn in direct competition with BTG in the United States as soon as possible after they receive FDA approval to do so.

124. This is consistent with public statements made by Respondent RDT that it intended to file its Biologics License Application ("BLA") for "Anavip" by 2013. See Exhibit 33.

125. On information and belief, Respondents RDT and Bioclon did, in fact, file a BLA for Antivipmyn/Anavip in April of 2013.

126. According to the FDA's Performance Goals and Procedures Guideline for the Prescription Drug User Fee Act (PDUFA), the FDA will act on Bioclon's BLA submission within 10.1 months after it is filed. Based on this schedule, Bioclon could have regulatory approval to market and sell Antivipmyn in the United States by as early as February 2014 if its BLA is treated as a Standard Application. If treated as a "Priority Application," the FDA's PDUFA Guidelines and its practice indicate that the FDA will act on Bioclon's BLA submission by November 2013.

127. BTG is informed and believes that, in anticipation of this approval to market and sell the Accused Products (Antivipmyn/Anavip) for human use in the United States, Bioclon has been and continues to make meaningful commitments and preparations to market and sell

Antivipmyn for human use in the United States. These commitments and preparations include market-seeding efforts, including: sponsoring and attending conferences concerning antivenoms in the United States where they promote Antivipmyn and discuss its future availability, and—even after submitting applications for FDA and USDA approval—submitting and publishing results from studies, including a head-to-head trial between CroFab® and Antivipmyn, and even sponsoring a phase 4 (i.e., postapproval) clinical study listed on the clinicaltrials.gov website of the United States National Institutes of Health. Exhibit 34.

128. Bioclon's market-seeding activities further include active marketing to zoos that maintain exotic snakes at their facilities and may need to administer antivenom to snake handlers or other animals. On its website, Bioclon states that, "in addition to the hospital market, its products are marketed for zoos around the world." Exhibit 35 (screen shot captured as of July 19, 2013). On information and belief, Bioclon uses RDT to distribute, and otherwise distributes, Antivipmyn to zoos in the United States. Bioclon's established relationship (including its use of RDT) to distribute Antivipmyn to zoos in the United States further prepares Bioclon to sell Antivipmyn immediately upon FDA approval.

129. Bioclon's U.S. market-seeding activities to date have been successful in that, even without the benefit of FDA or USDA approval, Bioclon has sold significant numbers of vials of the Accused Products in the United States. All such sales in the United States are outside the scope of Bioclon's research studies in support of its efforts to obtain FDA and USDA approval. The sale and use of these Accused Products in the United States has allowed Bioclon to obtain an improper head start in achieving market acceptance prior to FDA approval.

130. These activities and announcements indicate that Bioclon has committed to and anticipates selling the Accused Products, including Antivipmyn for human use, in the United

States before mid-2014 and that Bioclon's infringement of the '414 patent through FDA-approved sales of Antivipmyn for human use is imminent.

E. Specific Instances of Laboratorios Silanes' Unlawful Importation and Sale

131. On information and belief, Laboratorios Silanes oversees the importation and sale of the Accused Products into the United States through one or more of the Respondents.

132. On information and belief, Laboratorios Silanes is a corporate affiliate to Bioclon.

133. On information and belief, Antonio Lopez de Silanes is the Chief Executive Officer of Laboratorios Silanes. Exhibit 36 (screen shot captured as of July 19, 2013). As alleged in ¶ 95 above, Antonio Lopez de Silanes is also an acting executive officer for BioVeteria.

134. At a minimum, the above evidence demonstrates that Laboratorios Silanes is, in part, responsible for importing the Accused Products into the United States from Mexico.

F. Specific Instances of Silanes Group's Unlawful Importation and Sale

135. On information and belief, Silanes Group oversees the importation and sale of the Accused Products into the United States through one or more of the Respondents.

136. On its website, Silanes Group states, "Silanes Group is a corporation that comprises various companies that aim to fully accomplish our mission of providing healthcare solutions to the world." The website goes on to list Laboratorios Silanes and Bioclon as "Silanes Group's companies." Exhibit 11.

137. On its website, Silanes Group describes Laboratorios Silanes as "A Silanes Group company with 70 years of expertise in the domestic pharmaceutical market, and over 40 years of international presence in Central America and the Caribbean, and most recently, 5 years in Brazil and other Latin American countries." Exhibit 11.

138. On its website, Silanes Group describes Bioclon as "The Bioclon Institute, founded in 1990, belongs to Silanes Group and is a world leader in the production and research and development of Fabotherapics (safe and effective antivenoms against poisonous animals' bites and stings), manufactured with the Institute's own technology which is well-known all over the world." Exhibit 11.

139. On information and belief, Antonio Lopez de Silanes is the Chief Executive Officer of Silanes Group. Exhibit 36. As alleged in ¶¶ 21, 24 and 30 above, Antonio Lopez de Silanes is also an acting executive officer for Veteria Labs, BioVeteria and Bioclon.

140. At a minimum, the above evidence demonstrates that Silanes Group is, in part, responsible for importing the Accused Products into the United States from Mexico.

G. Specific Instances of RDT's Unlawful Importation and Sale

141. On information and belief, RDT partners with Bioclon to bring the Accused Products to market in the United States. On its website, RDT states that it "has entered into a joint development and distribution agreement with Instituto Bioclon, S.A. De C.V., a large, well established Mexican biotechnology company, to develop a series of much needed, high quality antivenoms for the United States and Canada." Exhibit 12 (screenshot captured as of July 19, 2013).

142. One such product of this joint development effort is "Anavip" described on RDT's website as "Crotalinae (pit viper) equine immune $F(ab')_2$ antivenom used in the treatment of envenomation by Crotaline snakes. It contains venom-specific antigen binding fragments derived from equine hyperimmune plasma. These fragments bind to venom thereby preventing or reversing the local and systemic effects of pit viper envenomation." Exhibit 12.

143. On information and belief, RDT unlawfully imports the Accused Products, including Anavip and/or Antivipmyn into the United States for marketing and/or distribution in this country.

144. On further information and belief, RDT and Bioclon have engaged in joint development, marketing and distribution efforts for other products in an effort to bring such Mexican orphan drugs to market in the United States. RDT presently markets and sells Bioclon's Anascorp product, described on RDT's website as "[Centruroides (Scorpion) Immune F(ab')2 (Equine) Injection], a Centruroides immune $F(ab')_2$ is the first of a series of antivenoms in the Rare Disease Therapeutics, Inc., pipeline. Anascorp®, an $F(ab')_2$ antibody, is FDA approved for the treatment of scorpion envenomation from the Centruroides scorpions. Centruroides sculpturatus is the only scorpion species with vertebrate neurotoxins whose natural range includes the United States." Exhibit 37 (screen shot captured as of July 19, 2013).

145. On information and belief, Bioclon's Antivipmyn Accused Product is also in RDT's pipeline to bring to market in the United States.

146. At a minimum, the above evidence demonstrates that RDT is responsible for facilitating the import into the United States from Mexico and subsequently distributing the Accused Products in the United States.

H. Specific Instances of Accredo's Unlawful Importation and Sale

147. On information and belief, Accredo is the United States distributor for Anascorp®, a product manufactured by Bioclon for the treatment of scorpion bites. See Exhibit 38. On information and belief, Accredo will become the United States distributor for Antivipmyn, if and when the product receives FDA approval.

148. In summary, on information and belief, Respondents have imported and are importing into the United States the Accused Products. In addition, Respondents have used and are using the imported Accused Products, including Antivipmyn and/or substantially similar compositions, in the United States to treat patients who have suffered rattlesnake envenomation in the United States, and they are inducing veterinarians, health care professionals, and others to treat patients with the Accused Products.

VI. UNLAWFUL AND UNFAIR ACTS COMMITTED BY RESPONDENTS: PATENT INFRINGEMENT

149. On information and belief, and as detailed below, Respondents manufacture abroad, sell for importation into the United States, import into the United States, and/or sell within the United States after importation, Accused Products that infringe one or more claims of the '414 patent.

A. Unlawful and Unfair Acts Committed by Veteria Labs

150. On information and belief, Respondent Veteria Labs directly infringes and will continue to directly infringe the '414 patent by making, using, selling, offering for sale, and importing antivenom compositions covered by claims of the '414 patent.

151. On information and belief, Veteria Labs manufactures and imports into the United States Accused Products, which directly infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 15, 16, 17, and 19 of the '414 patent.

152. Further, on information and belief, Veteria Labs indirectly infringes at least claims 21 and 22 of the '414 patent under 35 U.S.C. § 271(b) and (c) as a result of importing into and/or marketing the Accused Products (which lack any substantial non-infringing use) in the United States. Veteria Labs directs and thereby induces veterinarians, health care professionals

and others to administer Accused Products to patients who directly infringe at least claims 21 and 22.

153. Veteria Labs also directly instructs consumers how to purchase, import and utilize Accused Products in the treatment of rattlesnake bites.

154. Further, Veteria Labs either (1) already has actual knowledge of the '414 patent or (2) will acquire such actual knowledge no later than the service date of BTG's complaint.

155. In summary, Veteria Labs unlawfully manufactures and sells for importation into the United States Accused Products and products containing the same, that directly or indirectly infringe one or more claims of the '414 patent.

B. Unlawful and Unfair Acts Committed By Bioclon

156. On information and belief, Respondent Bioclon directly infringes and will continue to directly infringe the '414 patent by making, using, selling, offering for sale, and importing into the United States antivenom compositions covered by claims of the '414 patent.

157. On information and belief, Bioclon manufactures and imports into the United States Accused Products, which directly infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 15, 16, 17, 18, and 19 of the '414 patent.

158. Further, on information and belief, Bioclon indirectly infringes at least claims 21 and 22 of the '414 patent under 35 U.S.C. § 271(b) and (c) as a result of importing into and/or marketing the Accused Products (which lack any substantial non-infringing use) in the United States. Bioclon directs and thereby induces veterinarians, health care professionals and others to administer Accused Products to patients who directly infringe at least claims 21 and 22.

159. Further, Bioclon either (1) already has actual knowledge of the '414 patent or (2) will acquire such actual knowledge no later than the service date of BTG's complaint. For

example, on information and belief, Bioclon owns by assignment U.S. Patent Nos. 6,709,655, 7,485,303, 8,075,893 ("the '893 patent"), and 8,512,706 ("the '706 patent"), each of which cites and makes assertions regarding U.S. Patent No. 4,849,352 ("the '352 patent"). The '352 patent issued from the '629 application and is thus the ancestor of the '414 patent. In addition, when prosecuting the '893 patent and the '706 patent, Bioclon cited and discussed the case In re John B. Sullivan and Findlay F. Russell, 498 F.3d 1345 (Fed. Cir. 2007). The Sullivan case concerned the application that later issued as the '414 patent.

160. In summary, Bioclon unlawfully manufactures and sells for importation into the United States Accused Products and products containing the same, that directly or indirectly infringe one or more claims of the '414 patent.

C. Unlawful and Unfair Acts Committed by BioVeteria

161. On information and belief, Respondent BioVeteria directly infringes and will continue to directly infringe the '414 patent by making, using, selling, offering for sale, or importing antivenom compositions covered by claims of the '414 patent.

162. On information and belief, BioVeteria imports, distributes, uses and sells in the United States Accused Products, which directly infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 15, 16, 17, and 19 of the '414 patent.

163. Further, on information and belief, BioVeteria indirectly infringes at least claims 21 and 22 of the '414 patent under 35 U.S.C. § 271(b) and (c) as a result of importing into and/or marketing the Accused Products (which lack any substantial non-infringing use) in the United States. BioVeteria directs and thereby induces veterinarians, health care professionals and others to administer Accused Products to patients who directly infringe at least claims 21 and 22.

164. Further, BioVeteria either (1) already has actual knowledge of the '414 patent or (2) will acquire such actual knowledge no later than the service date of BTG's complaint.

165. In summary, BioVeteria unlawfully sells and distributes the Accused Products and products containing the same, that directly or indirectly infringe one or more claims of the '414 patent.

D. Unlawful and Unfair Acts Committed by Laboratorios Silanes

166. On information and belief, Respondent Laboratorios Silanes directly infringes and will continue to directly infringe the '414 patent by making, using, selling, offering for sale, or importing antivenom compositions covered by claims of the '414 patent.

167. On information and belief, Laboratorios Silanes imports, distributes, uses and sells in the United States Accused Products, which directly infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 15, 16, 17, 18, and 19 of the '414 patent.

168. Further, on information and belief, Laboratorios Silanes indirectly infringes at least claims 21 and 22 of the '414 patent under 35 U.S.C. § 271(b) and (c) as a result of importing into and/or marketing the Accused Products (which lack any substantial non-infringing use) in the United States. Laboratorios Silanes directs and thereby induces veterinarians, health care professionals and others to administer Accused Products to patients who directly infringe at least claims 21 and 22.

169. Further, Laboratorios Silanes either (1) already has actual knowledge of the '414 patent or (2) will acquire such actual knowledge no later than the service date of BTG's complaint.

170. In summary, Laboratorios Silanes unlawfully sells and distributes the Accused Products and products containing the same, that directly or indirectly infringe one or more claims of the '414 patent.

E. Unlawful and Unfair Acts Committed by Silanes Group

171. On information and belief, Respondent Silanes Group directly infringes and will continue to directly infringe the '414 patent by making, using, selling, offering for sale, or importing antivenom compositions covered by claims of the '414 patent.

172. On information and belief, Silanes Group imports, distributes, uses and sells in the United States Accused Products, which directly infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 15, 16, 17, 18, and 19 of the '414 patent.

173. Further, on information and belief, Silanes Group indirectly infringes at least claims 21 and 22 of the '414 patent under 35 U.S.C. § 271(b) and (c) as a result of importing into and/or marketing the Accused Products (which lack any substantial non-infringing use) in the United States. Silanes Group directs and thereby induces veterinarians, health care professionals and others to administer Accused Products to patients who directly infringe at least claims 21 and 22.

174. Further, Silanes Group either (1) already has actual knowledge of the '414 patent or (2) will acquire such actual knowledge no later than the service date of BTG's complaint.

175. In summary, Silanes Group unlawfully sells and distributes the Accused Products and products containing the same, that directly or indirectly infringe one or more claims of the '414 patent.

F. Unlawful and Unfair Acts Committed by RDT

176. On information and belief, Respondent RDT directly infringes and will continue to directly infringe the '414 patent by making, using, selling, offering for sale, and/or importing antivenom compositions covered by claims of the '414 patent.

177. On information and belief, RDT imports and distributes into the United States Accused Products, which directly infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 15, 16, 17, 18, and 19 of the '414 patent.

178. Further, RDT either (1) already has actual knowledge of the '414 patent or (2) will acquire such actual knowledge no later than the service date of BTG's complaint.

179. In summary, RDT unlawfully imports and distributes within the United States Accused Products and products containing the same, that directly or indirectly infringe one or more claims of the '414 patent.

G. Unlawful and Unfair Acts Committed by Accredo

180. On information and belief, Respondent Accredo directly infringes and will continue to directly infringe the '414 patent by making, using, selling, offering for sale, and/or importing antivenom compositions covered by claims of the '414 patent.

181. On information and belief, Accredo distributes or has imminent plans to distribute within the United States Accused Products, which directly infringe at least claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 15, 16, 17, 18, and 19 of the '414 patent.

182. Further, Accredo either (1) already has actual knowledge of the '414 patent or (2) will acquire such actual knowledge no later than the service date of BTG's complaint.

183. In summary, Accredo unlawfully distributes or imminently will distribute within the United States Accused Products and products containing the same, that directly or indirectly infringe one or more claims of the '414 patent.

H. Summary of Infringement of the '414 patent by the Accused Products Imported by Respondents

184. A sample claim chart comparing each asserted independent claim of the '414 patent to the Accused Products is attached as Exhibit 3.

185. Further discovery may reveal that other products manufactured, sold for importation into the United States, imported into the United States, and/or sold after importation within the United States by Respondents infringe the claims of the '414 patent. Further discovery may also reveal that additional claims of the '414 patent are infringed by Respondents' products.

VII. THE DOMESTIC INDUSTRY

186. A domestic industry exists in the United States as required by 19 U.S.C. § 1337(a)(3)(A), (B) and (C) because BTG and/or its predecessors, Tab Inc. and Protherics Inc., have made (1) significant investment within the United States in plants and equipment, (2) significant employment within the United States of labor or capital, and/or (3) substantial investment within the United States in the exploitation of the '414 patent, including research and development, and engineering. Specific, non-limiting examples of such investments are provided below and set forth in greater detail in Exhibit 5, the Confidential Declaration of Matthew Gantz (with confidential attachments), filed herewith.[3]

[3] This complaint and the Confidential Gantz Declaration are based on information that was current as of at least the conclusion of BTG's fiscal year 2013, which ended on March 31, 2013. BTG will continue to provide current information.

187. Complainant BTG International Inc. is a leading specialist pharmaceutical company that is incorporated in Delaware with its principal offices in West Conshohocken, Pennsylvania (outside Philadelphia). Confidential Exhibit 5, Gantz Decl., ¶ 6. BTG International Inc. has three wholly-owned subsidiaries: Protherics UK Ltd, BTG Australasia Pty, and Protherics Utah Inc. Protherics UK Ltd has its principal place of business in Wales, while BTG Australasia Pty has its principal place of business in Australia. Protherics Utah Inc. has its principal offices in Salt Lake City, Utah. For purposes of domestic industry, "BTG" refers to BTG International Inc. and its wholly-owned subsidiaries.

188. BTG's most successful specialty pharmaceutical is CroFab®, the only FDA approved treatment for envenomation by North American pit vipers, a problem that uniquely affects Americans. Exhibit G6, 2012 Annual Report at 3. In addition, BTG has devoted significant resources into seeking USDA approval to market CroFab® for veterinary use under the name CroVet®. Confidential Exhibit 5, Gantz Decl., ¶ 23.

189. Exhibit 39 is a claim chart comparing CroFab® and CroVet® to claims 1, 20, and 21 of the '414 patent.

A. Development of CroFab®

190. The invention in the '414 patent was conceived and reduced to practice in the United States by Drs. John B. Sullivan and Findlay Russell. From 1974 until 1984, Dr. Sullivan served as the Associate Director of the Rocky Mountain Poison Control Center in Denver, Colorado. In that capacity, Dr. Sullivan was on call 24 hours a day for poisoning emergencies, many of which were the result of snake bites and subsequent envenomation. In 1982, in search of a safer, more effective antivenom, Dr. Sullivan joined Dr. Findlay Russell at the University of Southern California, where Dr. Sullivan worked with Dr. Russell and his team during the day

and spent nights in the laboratory developing an IgG antibody that would serve as the source for Fab fragments that bind the venom of crotalid snakes. In 1984, Dr. Sullivan and Dr. Russell conducted experiments showing that the Fab fragments were unexpectedly superior to ACP at preventing mortality in mice caused by crotalid venom. Sullivan and Russell then filed the patent application that would ultimately lead to the '414 patent.

191. Once initial studies revealed that their invention could be therapeutically effective, Dr. Sullivan and Dr. Russell partnered with Therapeutic Antibodies Inc. ("TAb Inc.") to commercialize their invention. In January of 1994, the Department of Health and Human Services approved CroFab® (then called CroTAb) as an orphan drug. Exhibit 6. In the mid-90's, TAb Inc. conducted the initial clinical trial for CroFab® (then called CroTAb) in the United States. In 1999, TAb Inc. merged with Proteus International to form Protherics Inc. And in October 2000, CroFab® was approved by the FDA for use in the treatment of minimal and moderate North American Crotalidae envenomation. Exhibit 40, Oct. 2, 2000 Approval Letter. The FDA subsequently expanded the indication for CroFab® to the management of patients with North American crotalid envenomation, without limitation to the degree of envenomation. Exhibit 41, CroFab® Prescribing Information (CroFab® Package Insert). CroFab® remains the only drug in the United States that is currently marketed and approved for its indication. Exhibit G6, 2012 Annual Report at 3. BTG purchased Protherics Inc. in 2008. Exhibit 42, 2009 Annual Report at 4.

B. CroFab® Production

192. CroFab® production is a complex, highly-regulated process that begins with venom extraction. BTG obtains the venom used to make CroFab® by milking snakes BTG maintains at its own snake farm in Salt Lake City, Utah. Paragraphs 13 and 19 of the

Confidential Gantz Declaration provide details about the physical plant, labor, and other expenditures related to the venom extraction and classification process that is foundational CroFab®. See Confidential Exhibit 5.

193. The venom obtained in Utah is shipped to a BTG facility in Wales and converted into immunogens that are then shipped to a BTG facility in Australia and injected into sheep, which are bled monthly. Exhibit G6, 2012 Annual Report at 26. The blood is converted to serum (the liquid component), which is frozen and shipped to a BTG facility in Wales and processed into a drug substance. *Id.*

194. The critical finishing steps necessary to convert the drug substance into a saleable pharmaceutical are performed in Baltimore, Maryland, by Cangene Biologics Inc. ("CBI"), a contractor hired by BTG. Under highly regulated conditions, CBI filters the drug substance, fills vials, and freeze dries the vials with appropriate dose amounts before labeling and packaging them for shipping. In addition, CBI, in conjunction with BTG, performs important testing and quality control operations at each stage of the conversion process. Paragraphs 18 and 19 of the Confidential Gantz Declaration provide details about the physical plant, labor, and other expenditures related to the critical finishing steps performed in Baltimore. See Confidential Exhibit 5.

C. Research and Development Related to CroFab®

195. BTG continues to invest significantly in research and development related to CroFab®. In addition to significant investments in research and development related to the CroFab® production process, BTG has undertaken a clinical trial program in the United States to assess the efficacy of CroFab® in treating envenomation by copperhead snakes. Also, BTG invests substantial resources in FDA regulatory compliance required to keep CroFab® on the

U.S. market. In addition, BTG has invested in research that will allow BTG to market CroFab® as CroVet®, for veterinary use in the United States. Paragraphs 20 through 23 of the Confidential Gantz Declaration provide details about BTG's domestic investments in research and development. See Confidential Exhibit 5.

D. Labor Related to CroFab® Training and Sales

196. Until recently, CroFab® was sold in the United States through distributors. In 2010, however, BTG made a significant investment in developing a direct sales approach—hiring and training a large team of Acute Care Specialists who train healthcare providers on the signs and symptoms of Crotalidae envenomation and appropriate use of CroFab®. All of BTG's Acute Care Specialists are in the United States. Paragraphs 26 through 28 of the Confidential Gantz declaration provide details about BTG's investment in domestic labor related to BTG's sales and training efforts related to CroFab®. See Confidential Exhibit 5.

E. Education

197. Finally, BTG invests significant resources in educating medical and academic communities in the United States about crotalid envenomation and CroFab® through grants and other educational programs. BTG has three Medical Science Liaisons; employees who devote at least half of their time responding to inquiries from healthcare providers and other educational tasks related to CroFab®. Paragraphs 24 and 25 of the Confidential Gantz declaration provide details concerning labor and other expenses related to education and marketing. See Confidential Exhibit 5.

VIII. HARMONIZED TARIFF SCHEDULE ITEM NUMBERS

198. On information and belief, the Harmonized Tariff Schedule of the United States item number under which the infringing pharmaceutical compositions and products containing the same may be imported into the United States include at least 3002.10.02.

IX. SAMPLE ARTICLES

199. Because the Accused Products in this case are chemical compositions and pharmaceutical drug products for the treatment of snake bite envenomation, BTG will not provide a sample of the domestic articles or the Accused Products unless specifically requested to do so. BTG is, however, providing with this Complaint a photograph of a sample of the domestic article and photocopies of the packaging and package insert that accompany a sample of the Accused Product. See Exhibit 24.

X. RELIEF REQUESTED

200. WHEREFORE, by reason of the foregoing, BTG respectfully requests that the United States International Trade Commission:

a. Institute an immediate investigation, pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(a)(1)(B)(i) and (b)(1), with respect to violations of Section 337 based upon the importation, sale for importation, and sale after importation into the United States of the Accused Products that infringe one or more of the asserted claims of the '414 patent;

b. Schedule and conduct a hearing, pursuant to 19 U.S.C. § 1337(c), for purposes of receiving evidence and hearing argument concerning whether there has been a violation of Section 337 of the Tariff Act of 1930, as amended; and, following the hearing, determine that there has been a violation of Section 337 of the Tariff Act of 1930, as amended;

c. Issue a permanent limited exclusion order pursuant to 19 U.S.C. § 1337(d)(1) excluding from entry into the United States all Accused Products and other formulations that infringe the '414 patent, excepts as authorized or otherwise under license by BTG;

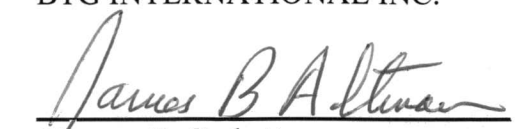
d. Issue permanent cease and desist orders, pursuant to 19 U.S.C. § 1337(f), directing Respondents and any of their principals, stockholders, officers, directors, employees, agents, licensees, distributors, controlled (whether by stock ownership or otherwise) or majority-owned business entities, successors, and assigns, from either directly engaging in or for, with or otherwise on behalf of Respondents, (A) importing or selling for importation into the United States the Accused Products or other formulations that infringe one or more claims of the '414 patent; (B) marketing, distributing offering for sale (including via the Internet or electronic mail), selling or otherwise transferring, in the United States imported Accused Products or other formulations that infringe one or more claims of the '414 patent; (C) advertising in the United States imported Accused Products or substantially similar formulations prepared therefrom that infringe one or more claims of the '414 patent; (D) soliciting U.S. agents or distributors for Accused Products or other formulations that infringe one or more claims of the '414 patent; or (E) aiding or abetting other entities in the importation, sale for importation, sale after importation, transfer, or distribution of Accused Products or other formulations in the United States that infringe one or more claims of the '414 patent; and

e. Grant any and all further relief as the Commission deems just and proper based on the facts determined by the investigation and the authority of the Commission.

Date: October 30, 2013

Respectfully Submitted,

BTG INTERNATIONAL INC.



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