IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, AND BAXTER HEALTHCARE S.A,)))
Plaintiffs,) Civil Action No. 1:14-cv-498
v.) JURY TRIAL DEMANDED
JOHNSON & JOHNSON, ETHICON, INC., FERROSAN MEDICAL DEVICES A/S, AND PACKAGING COORDINATORS, INC.)))
Defendants.)

AMENDED COMPLAINT

Plaintiffs Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare S.A. (collectively, "Baxter"), through their attorneys, Kirkland & Ellis, bring this action against Defendants Johnson & Johnson, Ethicon, Inc. ("Ethicon"), Ferrosan Medical Devices A/S ("Ferrosan"), and Packaging Coordinators, Inc. ("PCI") (collectively, "Defendants") to obtain permanent injunctive relief, actual damages, treble damages, attorneys' fees, and costs for Defendants' infringement of Baxter's asserted patents.

NATURE OF THIS ACTION

1. This is an action arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.* and is brought by Baxter against Defendants for Defendants' infringement of U.S. Patent Nos. 6,063,061 ("the '061 patent"), 6,066,325 ("the '325 patent"), 8,303,981 ("the '981 patent"), 8,357,378 ("the '378 patent"), 8,512,729 ("the '729 patent"), and 8,603,511 ("the '511 patent") (collectively, "the Patents-in-Suit").

THE PARTIES

- 2. Baxter International Inc. and Baxter Healthcare Corporation are Delaware corporations with a principal place of business in Deerfield, Illinois. Baxter Healthcare S.A. is a Swiss corporation with a principal place of business in Opfikon, Switzerland.
- 3. On information and belief, Johnson & Johnson is a New Jersey corporation with a principal place of business in New Brunswick, New Jersey. On information and belief, Ethicon, a wholly owned subsidiary of Johnson & Johnson, is a New Jersey corporation with a principal place of business in Somerville, New Jersey. On information and belief, Ferrosan is a Danish corporation, with a principal place of business in Soeborg Denmark. On information and belief, PCI is a Delaware corporation with a principal place of business in Philadelphia, Pennsylvania.

JURISDICTION AND VENUE

- 4. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338 because this action arises under the patent laws of the United States, including 35 U.S.C. § 271 *et seq*.
- 5. The Court has personal jurisdiction over Defendants because, on information and belief, Defendants have transacted business in this judicial district and have committed acts of infringement in this judicial district.
 - 6. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

FACTUAL BACKGROUND

7. As a global healthcare company, Baxter applies a unique combination of expertise in medical devices, pharmaceuticals, and biotechnology to create products that advance patient care in the United States and worldwide. Baxter designs, develops, manufactures, markets, and supports various medical products, including biosurgery products such as delivery devices used

for hemostasis. These products are used by medical providers to, among other things, control bleeding during surgery and reduce tissue adhesion following surgery.

- 8. As a result of Baxter's continued commitment to scientific innovation, Baxter has remained at the forefront of the medical devices, pharmaceuticals, and biotechnology fields. For instance, Baxter's BioSurgery franchise originated in the 1990s and was the first to launch a hemostatic device in the United States in 1998. Today, Baxter's BioSurgery portfolio consists of a range of biological and synthetic products and delivery devices used for hemostasis, tissue sealing, adhesion reduction, hard tissue regeneration, as well as soft tissue repair and microsurgery products. These products advance surgical care for surgeons and their patients in the United States and more than 60 countries across the world.
- 9. One of Baxter's innovative biosurgery products is Floseal. Floseal is a hemostatic matrix indicated for use in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or conventional procedures is ineffective or impractical. Floseal is protected by the Patents-in-Suit.
- 10. The '061 patent, entitled "Fragmented Polymeric Compositions and Methods For Their Use," issued on May 16, 2000 to inventors Donald G. Wallace, Cary J. Reich, Narinder S. Shargill, Felix Vega, and A. Edward Osawa. The '061 patent issued from U.S. Patent App. Ser. No. 08/903,674, filed on July 31, 1997. A true and correct copy of the '061 patent, incorporated herein by reference, is attached at Exhibit A. Baxter is the owner by assignment of all right, title, and interest in and to the '061 patent and has standing and authority to bring this complaint for patent infringement.
- 11. The '325 patent, entitled "Fragmented Polymeric Compositions and Methods For Their Use," issued on May 23, 2000 to inventors Donald G. Wallace, Cary J. Reich, Narinder S.

Shargill, Felix Vega, and A. Edward Osawa. The '325 patent issued from U.S. Patent App. Ser. No. 09/032,370, filed on February 27, 1998. A true and correct copy of the '325 patent, incorporated herein by reference, is attached at Exhibit B. Baxter is the owner by assignment of all right, title, and interest in and to the '325 patent and has standing and authority to bring this complaint for patent infringement.

- 12. The '981 patent, entitled "Fragmented Polymeric Compositions and Methods For Their Use," issued on November 6, 2012 to inventors Donald G. Wallace, Cary J. Reich, Narinder S. Shargill, Felix Vega, A. Edward Osawa, and Zhen Qian-Wallis. The '981 patent issued from U.S. Patent App. Ser. No. 13/174,963, previously published on May 31, 2012 as U.S. Patent Pub. No. 2012/0134980. A true and correct copy of the '981 patent, incorporated herein by reference, is attached at Exhibit C. Baxter is the owner by assignment of all right, title, and interest in and to the '981 patent and has standing and authority to bring this complaint for patent infringement.
- Their Use," issued on January 22, 2013 to inventors Donald G. Wallace, Cary J. Reich, Narinder S. Shargill, Felix Vega, and A. Edward Osawa. The '378 patent issued from U.S. Patent App. Ser. No. 13/114,784, previously published on September 15, 2011 as U.S. Patent Pub. No. 2011/022323. A true and correct copy of the '378 patent, incorporated herein by reference, is attached at Exhibit D. Baxter is the owner by assignment of all right, title, and interest in and to the '378 patent and has standing and authority to bring this complaint for patent infringement.
- 14. The '729 patent, entitled "Fragmented Polymeric Compositions and Methods For Their Use," issued on August 20, 2013 to inventors Donald G. Wallace, Cary J. Reich, Narinder S. Shargill, Felix Vega, A. Edward Osawa, and Zhen Qian-Wallis. The '729 patent issued from

U.S. Patent App. Ser. No. 13/665,475, previously published on May 2, 2013 as U.S. Patent Pub. No. 2013/0108611. A true and correct copy of the '729 patent, incorporated herein by reference, is attached at Exhibit E. Baxter is the owner by assignment of all right, title, and interest in and to the '729 patent and has standing and authority to bring this complaint for patent infringement.

- Their Use," issued on December 10, 2013 to inventors Donald G. Wallace, Cary J. Reich, Narinder S. Shargill, Felix Vega, and A. Edward Osawa. The '511 patent issued from U.S. Patent App. Ser. No. 13/744,949, previously published on August 8, 2013 as U.S. Patent Pub. No. 2013/0204192. A true and correct copy of the '511 patent, incorporated herein by reference, is attached at Exhibit F. Baxter is the owner by assignment of all right, title, and interest in and to the '511 patent and, has standing and authority to bring this complaint for patent infringement.
- 16. Without the ability to enforce its intellectual property rights, such as those relating to its hemostasis devices at issue in this action, Baxter would not be able to sustain the extensive commitment to research and development that has enabled it to lead the way into numerous improvements across a broad range of technologies, including biosurgery technologies at issue in this action.
- 17. On information and belief, Defendants manufacture, import, assemble, and market delivery devices for hemostasis, such as the SurgiFlo family of products. On information and belief, the SurgiFlo hemostatic matrix is indicated for use in surgical procedures as an adjunct to hemostasis when control of bleeding by ligature or other conventional methods is ineffective or impractical.
- 18. On information and belief, Defendants work in concert to produce and/or market the SurgiFlo family of products to medical professionals. On information and belief, hospitals

and physicians purchase SurgiFlo from one or more Defendants and employ the product in the course of surgical procedures by delivering it to a target treatment site to inhibit bleeding in accordance with Defendants' instructions for use.

- 19. Defendants' SurgiFlo products directly compete with Baxter's biosurgery products, including the Floseal family of products, which practice the Patents-in-Suit. On information and belief, Defendants are aware of Floseal's established position in the hemostatic products market and carefully track Baxter's marketing and other activities related to the Floseal products in the United States and worldwide. For example, one or more of Defendants have repeatedly communicated with Baxter regarding competitive marketing issues in the United States and abroad pertaining to Floseal and SurgiFlo.
- 20. On information and belief, Defendants have infringed and will continue to infringe Baxter's intellectual property rights by making, using, selling, offering for sale within the United States and/or importing into the United States delivery products for hemostasis such as the SurgiFlo family of products.

COUNT I - INFRINGEMENT OF THE '061 PATENT

- 21. Baxter incorporates Paragraphs 1-20 of its Complaint as fully set forth herein.
- 22. On information and belief, Defendants have directly and/or indirectly infringed and will continue to infringe, either literally or under the doctrine of equivalents, one or more claims of the '061 patent pursuant to 35 U.S.C. § 271.
- 23. On information and belief, the offering to sell, sale, and/or importation by one or more of the Defendants of the SurgiFlo family of products actively induces infringement by medical professionals of one or more claims of the '061 patent.

- 24. On information and belief, Defendants' SurgiFlo products, when used as directed, are used by medical professionals in a manner that directly infringes one or more claims of the '061 patent either literally or under the doctrine of equivalents.
- 25. On information and belief, Defendants had actual notice of the existence of the '061 patent at least as of the filing of the Complaint. Moreover, Defendants had actual and/or constructive notice of the '061 patent through their long-standing participation in the hemostatic products market and because Baxter's Floseal products with which Defendants directly compete are marked with the '061 patent.
- 26. On information and belief, Defendants know of or are willfully blind to the fact that their actions with respect to Defendants' SurgiFlo family of products induce or contribute to the direct infringement of the '061 patent.
- 27. On information and belief, the use of Defendants' SurgiFlo family of products constitutes a material part of the invention recited in one or more claims of the '061 patent. On information and belief, Defendants' SurgiFlo products are especially made or adapted for use in infringing one or more claims of the '061 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants' SurgiFlo products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.
- 28. On information and belief, Defendants' offering to sell, sale, and/or importation of the SurgiFlo family of products contributorily infringes at least one claim of the '061 patent either literally or under the doctrine of equivalents.
- 29. On information and belief, by their promotional activities and package insert for SurgiFlo products, Defendants know or should know that they aid and abet another's direct infringement of at least one of the claims of the '061 patent.

- 30. On information and belief, Defendants' infringement of the '061 patent will continue, unless enjoined by this Court.
- 31. Baxter has been damaged by Defendants' infringement of the '061 patent and is suffering and will continue to suffer damages and irreparable harm as a result, unless the Court enjoins Defendants from continuing their activities.

COUNT II - INFRINGEMENT OF THE '325 PATENT

- 32. Baxter incorporates Paragraphs 1-31 of its Complaint as fully set forth herein.
- 33. On information and belief, Defendants have directly and/or indirectly infringed and will continue to infringe, either literally or under the doctrine of equivalents, one or more claims of the '325 patent pursuant to 35 U.S.C. § 271.
- 34. On information and belief, the offering to sell, sale, and/or importation by one or more of the Defendants of the SurgiFlo family of products actively induces infringement by medical professionals of one or more claims of the '325 patent.
- 35. On information and belief, Defendants' SurgiFlo products, when used as directed, are used by medical professionals in a manner that directly infringes one or more claims of the '325 patent either literally or under the doctrine of equivalents.
- 36. On information and belief, Defendants had actual notice of the existence of the '325 patent at least as of the filing of the Complaint. Moreover, Defendants had actual and/or constructive notice of the existence of the '325 patent at least through their long-standing participation in the hemostatic products market and because Baxter's Floseal products with which Defendants directly compete are marked with the '325 patent.
- 37. On information and belief, Defendants know of or are willfully blind to the fact that their actions with respect to Defendants' SurgiFlo family of products induce or contribute to the direct infringement of the '325 patent.

- 38. On information and belief, the use of Defendants' SurgiFlo family of products constitutes a material part of the invention recited in one or more claims of the '325 patent. On information and belief, Defendants know or should know that their SurgiFlo products are especially made or adapted for use in infringing one or more claims of the '325 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants' SurgiFlo products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.
- 39. On information and belief, Defendants' offering to sell, sale, and/or importation of the SurgiFlo family of products contributorily infringes at least one claim of the '325 patent either literally or under the doctrine of equivalents.
- 40. On information and belief, by their promotional activities and package insert for SurgiFlo products, Defendants know or should know that they aid and abet another's direct infringement of at least one of the claims of the '325 patent.
- 41. On information and belief, Defendants' infringement of the '325 patent will continue, unless enjoined by this Court.
- 42. Baxter has been damaged by Defendants' infringement of the '325 patent and is suffering and will continue to suffer damages and irreparable harm as a result, unless the Court enjoins Defendants from continuing their activities.

COUNT III - INFRINGEMENT OF THE '981 PATENT

- 43. Baxter incorporates Paragraphs 1-42 of its Complaint as fully set forth herein.
- 44. On information and belief, Defendants have directly and/or indirectly infringed and will continue to infringe, either literally or under the doctrine of equivalents, one or more claims of the '981 patent, pursuant to 35 U.S.C. § 271.

- 45. On information and belief, the offering to sell, sale, and/or importation by one or more of the Defendants of the SurgiFlo family of products actively induces infringement by medical professionals of one or more claims of the '981 patent.
- 46. On information and belief, Defendants' SurgiFlo products, when used as directed, are used by medical professionals in a manner that directly infringes one or more claims of the '981 patent either literally or under the doctrine of equivalents.
- 47. On information and belief, Defendants had actual notice of the '981 patent at least as of the filing of the Complaint and had actual and/or constructive notice of the existence of the '981 patent at least through their long-standing participation in the hemostatic products market.
- 48. On information and belief, Defendants know of or are willfully blind to the fact that their actions with respect to Defendants' SurgiFlo family of products induce or contribute to the direct infringement of the '981 patent.
- 49. On information and belief, the use of Defendants' SurgiFlo family of products constitutes a material part of the invention recited in one or more claims of the '981 patent. On information and belief, Defendants' SurgiFlo products are especially made or adapted for use in infringing one or more claims of the '981 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants' SurgiFlo products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.
- 50. On information and belief, Defendants' offering to sell, sale, and/or importation of the SurgiFlo family of products contributorily infringes at least one claim of the '981 patent either literally or under the doctrine of equivalents.
- 51. On information and belief, by their promotional activities and package insert for SurgiFlo products, Defendants know or should know that they aid and abet another's direct

infringement of at least one of the claims of the '981 patent.

- 52. On information and belief, Defendants' infringement of the '981 patent will continue, unless enjoined by this Court.
- 53. Baxter has been damaged by Defendants' infringement of the '981 patent and is suffering and will continue to suffer damages and irreparable harm as a result, unless the Court enjoins Defendants from continuing their activities.

COUNT IV - INFRINGEMENT OF THE '378 PATENT

- 54. Baxter incorporates Paragraphs 1-53 of its Complaint as fully set forth herein.
- 55. On information and belief, Defendants have directly and/or indirectly infringed and will continue to infringe, either literally or under the doctrine of equivalents, one or more claims of the '378 patent, pursuant to 35 U.S.C. § 271.
- 56. On information and belief, the offering to sell, sale, and/or importation by one or more of the Defendants of the SurgiFlo family of products actively induces infringement by medical professionals of one or more claims of the '378 patent.
- 57. On information and belief, Defendants' SurgiFlo, when used as directed, are used by medical professionals in a manner that directly infringes one or more claims of the '378 patent either literally or under the doctrine of equivalents.
- 58. On information and belief, Defendants had actual knowledge of the '328 patent at least as of the filing of the Complaint and had actual and/or constructive notice of the existence of the '378 patent at least through their long-standing participation in the hemostatic products market.
- 59. On information and belief, Defendants know of or are willfully blind to the fact that their actions with respect to Defendants' SurgiFlo family of products induce or contribute to direct infringement of the '378 patent.

- 60. On information and belief, the use of Defendants' SurgiFlo family of products constitutes a material part of the invention recited in one or more claims of the '378 patent. On information and belief, Defendants know or should know that their SurgiFlo products are especially made or adapted for use in infringing one or more claims of the '378 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants' SurgiFlo products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.
- 61. On information and belief, Defendants' offering to sell, sale, and/or importation of the SurgiFlo family of products contributorily infringes at least one claim of the '378 patent either literally or under the doctrine of equivalents.
- 62. On information and belief, by their promotional activities and package insert for SurgiFlo products, Defendants know or should know that they aid and abet another's direct infringement of at least one of the claims of the '378 patent.
- 63. On information and belief, Defendants' infringement of the '378 patent will continue, unless enjoined by this Court.
- 64. Baxter has been damaged by Defendants' infringement of the '378 patent and is suffering and will continue to suffer damages and irreparable harm as a result, unless the Court enjoins Defendants from continuing their activities.

COUNT V - INFRINGEMENT OF THE '729 PATENT

- 65. Baxter incorporates Paragraphs 1-64 of its Complaint as fully set forth herein.
- 66. On information and belief, Defendants have directly and/or indirectly infringed and will continue to infringe, either literally or under the doctrine of equivalents, one or more claims of the '729 patent, pursuant to 35 U.S.C. § 271.

- 67. On information and belief, the offering to sell, sale, and/or importation by one or more of the Defendants of the SurgiFlo family of products actively induces infringement by medical professionals of one or more claims of the '729 patent.
- 68. On information and belief, Defendants' SurgiFlo, when used as directed, are used by medical professionals in a manner that directly infringes one or more claims of the '729 patent either literally or under the doctrine of equivalents.
- 69. On information and belief, Defendants had actual knowledge of the existence of the '729 patent at least as of the filing of the Complaint and had actual and/or constructive notice of the existence of the '729 patent at least through their long-standing participation in the hemostatic products market.
- 70. On information and belief, Defendants know of or are willfully blind to the fact that their actions with respect to Defendants' SurgiFlo family of products induce or contribute to the direct infringement of the '729 patent.
- 71. On information and belief, the use of Defendants' SurgiFlo family of products constitutes a material part of the invention recited in one or more claims of the '729 patent. On information and belief, Defendants' SurgiFlo products are especially made or adapted for use in infringing one or more claims of the '729 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants' SurgiFlo products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.
- 72. On information and belief, Defendants' offering to sell, sale, and/or importation of the SurgiFlo family of products contributorily infringes at least one claim of the '729 patent either literally or under the doctrine of equivalents.

- 73. On information and belief, by their promotional activities and package insert for SurgiFlo products, Defendants know or should know that they aid and abet another's direct infringement of at least one of the claims of the '729 patent.
- 74. On information and belief, Defendants' infringement of the '729 patent will continue, unless enjoined by this Court.
- 75. Baxter has been damaged by Defendants' infringement of the '729 patent and is suffering and will continue to suffer damages and irreparable harm as a result, unless the Court enjoins Defendants from continuing their activities.

COUNT VI - INFRINGEMENT OF THE '511 PATENT

- 76. Baxter incorporates Paragraphs 1-75 of its Complaint as fully set forth herein.
- 77. On information and belief, Defendants have directly and/or indirectly infringed and will continue to infringe, either literally or under the doctrine of equivalents, one or more claims of the '511 patent, pursuant to 35 U.S.C. § 271.
- 78. On information and belief, the offering to sell, sale, and/or importation by one or more of the Defendants of the SurgiFlo family of products actively induces infringement by medical professionals of one or more claims of the '511 patent.
- 79. On information and belief, Defendants' SurgiFlo family of products, when used as directed, are used by medical professionals in a manner that directly infringes one or more claims of the '511 patent either literally or under the doctrine of equivalents.
- 80. On information and belief, Defendants had actual knowledge of the '511 patent at least as of the filing of the Complaint and had actual and/or constructive notice of the existence of the '511 patent at least through their long-standing participation in the hemostatic products market.

81. On information and belief, Defendants know of or are willfully blind to the fact that their actions with respect to Defendants' SurgiFlo family of products induce or contribute to direct infringement of the '511 patent.

82. On information and belief, the use of Defendants' SurgiFlo family of products constitutes a material part of the invention recited in one or more claims of the '511 patent. On information and belief, Defendants know or should know that their SurgiFlo products are especially made or adapted for use in infringing one or more claims of the '511 patent, either literally or under the doctrine of equivalents. On information and belief, Defendants' SurgiFlo products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

83. On information and belief, Defendants' offering to sell, sale, and/or importation of the SurgiFlo family of products contributorily infringes at least one claim of the '511 patent either literally or under the doctrine of equivalents.

84. On information and belief, by their promotional activities and package insert for SurgiFlo products, Defendants know or should know that they aid and abet another's direct infringement of at least one of the claims of the '511 patent.

85. On information and belief, Defendants' infringement of the '511 patent will continue, unless enjoined by this Court.

86. Baxter has been damaged by Defendants' infringement of the '511 patent and is suffering and will continue to suffer damages and irreparable harm as a result, unless the Court enjoins Defendants from continuing their activities.

REQUEST FOR RELIEF

WHEREFORE, Baxter prays for judgment as follows:

(a) That Defendants have infringed and continue to infringe, directly, contributorily, and/or by inducement, the Patents-in-Suit;

(b) That Defendants and their officers, agents, and employees, and those persons in active concert or participation with any of them, and their successors and assigns be preliminarily and permanently enjoined from infringement, inducement of infringement, and contributory infringement of the Patents-in Suit, including but not limited to an injunction against making, using offering to sell, selling within the United States, and importing into the United States, any products covered by the Patents-in-Suit.

- (c) That judgment be entered awarding Baxter damages resulting from Defendants' infringement of the Patents-in-Suit in an amount no less than a reasonable royalty.
- (d) That Defendants' infringement of the Patents-in-Suit has been and continues to be willful, and awarding Baxter treble damages in light of Defendants' willful infringement;
- (e) That Baxter be awarded pre-judgment and post-judgment interest at the maximum rate allowed by law;
- (f) That this case be deemed exceptional and attorneys' fees be awarded pursuant to 35 U.S.C. § 285 and that Baxter be awarded its reasonable attorneys' fees, expenses, and costs incurred in connection with this action; and
- (g) That this Court order such other and further relief as the Court may deem just and proper.

JURY DEMAND

Baxter hereby demands trial by jury in this action on all issues so triable.

Dated: March 13, 2014 Respectfully submitted,

By: /s/ Mary E. Zaug

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