Bingham McCutchen LLP
Gary Adler
399 Park Avenue
New York, NY 10022-4689
Telephone: (212) 705-7000
Facsimile: (212) 752-5378
gary.adler@bingham.com

Bingham McCutchen LLP
Richard de Bodo (*pro hac vice* pending)
1601 Cloverfield Boulevard
Suite 2050 North
Santa Monica, CA 90404-4082
Telephone: (310) 907-1000
Facsimile: (310) 907-2000
rich.debodo@bingham.com

Attorneys for Plaintiffs Celltrion Healthcare Co., Ltd. and Celltrion, Inc.

14 CV 2256

United States District Court
Southern District Of New York

Celltrion Healthcare Co., Ltd., and Celltrion, Inc.,

Plaintiffs,

-against-

Kennedy Trust for Rheumatology Research (formerly known as The Mathilda and Terence Kennedy Institute of Rheumatology Trust),

Defendant.

Case No. _____

Complaint for Declaratory Judgment

Plaintiffs Celltrion Healthcare Co., Ltd. and Celltrion, Inc. (collectively "Celltrion"), through their undersigned counsel, bring this Complaint asserting and seeking Declaratory Judgment against Defendant Kennedy Trust for Rheumatology Research ("Kennedy"), formerly known as The Mathilda and Terence Kennedy Institute of Rheumatology Trust, and alleges on knowledge as to itself and otherwise on information and belief, as follows:

Nature of the Action.

1. For the last 12 years, Celltrion has, as its mission, pursued ways of supplying innovative monoclonal antibodies and other biopharmaceutical medicines at an affordable cost to patients suffering from life-threatening and debilitating diseases. Monoclonal antibodies are the only effective treatments for numerous diseases, but their high cost makes them unavailable to many patients.[1] To provide more affordable and accessible drugs for these patients, Celltrion and many other biopharmaceutical companies have attempted to create biosimilars for the most commonly prescribed monoclonal antibodies.[2] Even though it has been competing against many of the world's largest pharmaceutical companies, through a combination of cutting-edge, innovative science, skillfully designed clinical trials, and old-fashioned hard work and perseverance, Celltrion has emerged as the world leader in developing such biosimilars.

2. Celltrion's accomplishments in the biosimilars field are unrivaled. In 2012, Celltrion became the first company to successfully create and obtain regulatory approval under internationally accepted guidelines for a biosimilar monoclonal antibody product—

[1] Antibody treatments can cost $15,000 to $30,000 per patient annually.

[2] A biosimilar (or follow-on biologic) is a biological product that is highly similar to an already approved biological product in terms of its potency, purity, and safety, even though there may be minor differences in its clinically inactive components.

Remsima®. In January 2014, Celltrion followed that major achievement by obtaining the world's first approval, based on global clinical trials, of a biosimilar oncology monoclonal antibody. To date, no other biosimilar antibody product from any other company has been approved under internationally accepted guidelines.

3. Remsima® is a biosimilar for Janssen Biotech, Inc.'s ("Janssen's") Remicade®, Remicade® is approved in the United States for treating rheumatoid arthritis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and plaque psoriasis. Remicade® is very expensive; a single infusion in the United States typically costs thousands of dollars. Remsima® could provide millions of Americans suffering from multiple severe diseases a safe, effective and much more affordable treatment alternative.

4. This case relates to Remsima® and its introduction into the United States. Defendant Kennedy has obtained patents covering methods of treating rheumatoid arthritis by administering a combination of an anti-TNFα antibody (such as Remicade®) and the known rheumatoid arthritis drug methotrexate ("co-administration patents").[3] The U.S. Food & Drug Administration ("FDA") approved Remicade® for treating rheumatoid arthritis in conjunction with methotrexate in November 1999. Kennedy first applied for its co-administration patents in 1992, and the first of these patents to issue is now expired. Thus, under U.S. law, Kennedy's permissible patent protection period for its purported co-administration method should have ended. However, Kennedy used improper and manipulative tactics to obtain at least three other patents relating to the co-administration method—U.S. Patent Nos. 7,846,442 (the "'442 patent"), 8,298,537 (the "'537 patent") and

[3] An anti-TNFα antibody is an antibody that binds to the protein tumor necrosis factor-alpha ("TNFα") and neutralizes its activity. TNFα is a mediator of inflammatory diseases such as rheumatoid arthritis.

8,383,120 (the "'120 patent").[4] These patents are all invalid because they claim the same invention or obvious variations of the invention Kennedy claimed in the earlier, now expired, patent. Nevertheless, Kennedy has continued to aggressively enforce its patents and has asserted it intends to keep doing so until the last of them purportedly expires in 2018. By this action, Celltrion seeks a declaratory judgment that Kennedy's allegedly unexpired co-administration patents are invalid, thereby clearing the path for an affordable competitor to Remicade® to enter the U.S. market.

5. Celltrion intends to apply for marketing approval of Remsima® in the United States during the first half of 2014. Celltrion expects the U.S. Food & Drug Administration ("FDA") to approve Remsima® by early 2015 (assuming the approval process is not hindered by interference from Kennedy or its affiliates). Remsima® will become the first biosimilar of an antibody drug ever approved in the United States. Remsima® will provide millions of Americans suffering from chronic and difficult-to-treat diseases a safe, effective, and much more affordable alternative to Remicade® and other costly antibody drugs.

6. Celltrion is informed and believes that Kennedy's co-administration patents represent millions of dollars of revenue to Kennedy. Celltrion is informed and believes that Kennedy, which has no product of its own, has pursued an aggressive licensing campaign to secure a substantial royalty stream from manufacturers of anti-TNFα antibodies such as Janssen and AbbVie Inc. (the manufacturer of Humira®). Celltrion is informed and believes that Kennedy, in order to increase its royalty stream, has improperly attempted to extend the enforceability period of its co-administration patents, to obtain patents which should not have been awarded, and to enforce patents that are invalid.

[4] Copies of the '442, '537 and '120 patents are attached as Exhibits A-C.

7. Kennedy has made it clear through actions and public statements that it will assert its co-administration patents against any new entrant into the rheumatoid arthritis treatment market. Indeed, Kennedy has asserted the European and Canadian counterparts of its co-administration patents against Celltrion's biosimilar of Remicade® in the United Kingdom and Canada, and has expressly refused to grant Celltrion a license to its U.S. patents that would take effect when Celltrion requested. In view of these facts, Celltrion expects Kennedy will assert the '442, '537 and '120 patents against Remsima®.

8. Celltrion's plan to launch Remsima® in the United States upon receiving approval in early 2015 and to challenge Kennedy's improperly obtained patents, and Kennedy's scheme to assert its invalid co-administration patents, place Celltrion and Kennedy on an inevitable collision course. Thus, Celltrion now seeks a judicial declaration that, among other things, Kennedy's '442, '537 and '120 patents are invalid.

9. This controversy is a matter of great urgency. Celltrion is eager to launch Remsima® in the United States as soon as practicable after it receives FDA approval. Celltrion is eager to make Remsima® available to the millions of Americans who suffer from diseases Remsima® can treat. Moreover, Celltrion has invested enormous resources in Remsima® and is eager to begin receiving commercial returns on its investment. Because Celltrion expects to face patent infringement allegations from Kennedy, Celltrion wants to start the adjudicative process regarding the invalidity and unenforceability of Kennedy's patents. This will enable Celltrion to immediately avail itself of the processes available in the federal judiciary to discover information relating to Kennedy's patents, to learn Kennedy's claim constructions and infringement contentions, and to present issues speedily for adjudication and test the validity and enforceability of Kennedy's patents.

Denying Celltrion the opportunity to litigate declaratory judgment claims now would delay Celltrion's access to the judicial system for about 10-12 months (and perhaps even longer). This delay could force Celltrion into a difficult choice between (a) launching Remsima® without the benefit of discoverable information regarding Kennedy's patents and legal positions, or (b) not launching Remsima® at the earliest opportunity and waiting for a delayed legal process to play out. An at-risk launch without the benefit of discovery could create serious risks and exposure for Celltrion and could subject it to substantial damages and significant commercial harm. Similarly, a decision by Celltrion to delay its launch of Remsima® would be harmful in several respects. It would harm the public interest because health care costs related to diseases for which Remicade® is currently the only available treatment would remain high. It would harm the interests of individual Americans who could benefit from the use of Remsima®. It also would cause Celltrion irreparable harm by depriving it of a return on its investment, significant revenues and profits arising from Remsima® sales, and other important business benefits.

The Parties.

10. Celltrion Healthcare Co., Ltd. and Celltrion, Inc. are companies organized and existing under the laws of the Republic of Korea. Celltrion, Inc. is a biopharmaceutical company that specializes in research and development of antibody biosimilars and novel biopharmaceuticals. Celltrion Healthcare Co., Ltd. markets and distributes such biopharmaceutical products in the United States. Celltrion Healthcare Co., Ltd. maintains its U.S. office in Cambridge, Massachusetts.

11. Celltrion is informed and believes that Kennedy is organized and exists under the laws of the United Kingdom, having a place of business in London, England. Celltrion is

informed and believes that Kennedy conducts business in this District, including, without limitation, business relating to the patents in suit. Celltrion is informed and believes that "the principal objective" of Kennedy is to "protect intellectual property created or acquired by the Trust." Celltrion is informed and believes that Kennedy presently claims to have right, title and interest in the '442, '537 and '120 patents and will assert them against Celltrion.

Jurisdiction and Venue.

12. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States of America, Title 35 of the U.S. Code. This Court has subject matter jurisdiction over this action under 28 U.S. §§ 1331 and 1338(a).

13. This Court has personal jurisdiction over Kennedy because, among other things, Celltrion is informed and believes that Kennedy conducts business in this District, including, without limitation, business regarding the patents-in-suit. Celltrion is further informed and believes that Kennedy has previously consented to personal jurisdiction in this judicial district for cases relating to the validity of certain claims of the '442, '537 and '120 patents.

14. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) because Kennedy is subject to personal jurisdiction in the Southern District of New York.

15. The validity of certain claims of the '442 and '120 patents has been challenged by AbbVie, Inc. in this Court in *AbbVie Inc., et al. v. The Mathilda and Terence Kennedy Institute of Rheumatology Trust*, Case No. 11-2541, and *AbbVie Inc., et al. v. The Kennedy Trust for Rheumatology Research*, Case No. 13-1358. This Court is familiar with issues relating to the validity of the claims of the '442 and '120 patents and the related '537 patent.

Celltrion's Development of Biosimilars Required Technical Innovation and Creativity, As Well As Investment of Significant Resources and Time.

Biosimilars are extremely complex products that are difficult to manufacture.

16. Developing biosimilars of monoclonal antibody drugs poses formidable technical challenges. Standard, small-molecule pharmaceuticals are significantly different from biologic drugs such as antibodies. Typically, biologic drugs are thousands of times larger than synthesized pharmaceuticals in terms of molecular size. Moreover, monoclonal antibodies have a complex structure that is influenced by, among other factors, the manufacturing process, their environment and any post-translational modifications. And even though a drug company aspiring to make a biosimilar may know the overall structure of a monoclonal antibody, it will not necessarily know the manufacturing platform the original manufacturer used to make the original biologic, due to the proprietary nature of the information.

17. Given these considerations, any differences in the biological system a drug developer uses to produce a biosimilar agent (in comparison to the system the originator used) will likely translate into subtle differences that could be difficult to characterize. Such variances can result in clinically relevant differences in efficacy, safety, and immunogenicity. Therefore, it is extremely difficult to make a biosimilar that truly is "biosimilar" to the originator's product. A drug company only can prove the required clinical biosimilarity through extensive R&D and clinical trials.

18. Furthermore, because biosimilars of antibody drugs are complex and are manufactured in living cells, the consistent manufacture of safe and effective biosimilars

requires significant technical skill and resource investment. The U.S. Federal Trade Commission has stated that while it typically takes drug companies about 3-5 years and an investment of about $1-5 million to develop a generic drug, developing a biosimilar could take as much as 8-10 years and cost $100-200 million.

Celltrion overcame great challenges in developing Remsima®.

19. In 2008, Celltrion decided to tackle the challenges associated with developing monoclonal antibody drugs and began work on Remsima® (and other biologic drug targets). The company expended significant resources to gain the technical expertise needed to design and manufacture the product. To date, Celltrion has invested more than $112 million in out-of-pocket external costs, as well as significant internal manpower and other corporate resources, in its Remsima® program.

20. Celltrion's R&D efforts relating to Remsima® produced several technological breakthroughs. For example, Celltrion developed a patented system for introducing the "instructions" for its biologic products into the cells that produce the drugs.[5] This critical innovation allowed Celltrion to efficiently and reliably produce its molecules. Celltrion also developed unique and proprietary cell lines and manufacturing and purification processes that enabled it to produce significant quantities of high-quality biologic drug products.

21. Due to its ingenuity, technical expertise, commitment and focus, Celltrion has become a recognized global leader in biosimilar development. Many of the world's largest

[5] Antibody drugs such as Remsima® are a type of protein. Proteins are large biological molecules that comprise strings of building blocks called amino acids. To manufacture such proteins, DNA encoding the proteins (*i.e.*, providing the instructions for the amino acid sequence) must be inserted into the host cell, which then uses its innate protein-making machinery to generate the antibody drug. Inserting the DNA instructions into the host cell in a way that allows the host cell to make many copies of the antibody drug is therefore a critical step in the manufacture of antibody drugs.

pharmaceutical companies—*e.g.*, Merck, Amgen, Biogen Idec, Boehringer Ingelheim, Novartis/Sandoz, Samsung, and Actavis—have publicly announced they are pursuing biosimilar products. But Celltrion has outpaced these larger and more established competitors to produce the world's first antibody-based biosimilar products that have been demonstrated to be safe and effective in global clinical trials. Celltrion received approval for its first biosimilar product (Remsima®) from the Korean Ministry of Food and Drug Safety ("MFDS") in 2012. The European Medicines Agency ("EMA") followed by approving Remsima® in 2013. This year, Celltrion obtained regulatory approval in Korea for its second biosimilar monoclonal antibody product.

22. Celltrion has been recognized for its commitment to quality and innovation. In 2009, the U.S. Centers for Disease Control and Prevention asked Celltrion to co-develop antibodies for the treatment of rabies and seasonal/pandemic influenza. In 2013, Celltrion's candidate influenza therapy obtained positive Phase I clinical trial results, which confirmed that the candidate is safe and well tolerated.

There is a great public need for the earliest possible availability of Remsima® to Americans suffering from rheumatoid arthritis.

23. There is an urgent need for more affordable treatments for Americans suffering from rheumatoid arthritis. Rheumatoid arthritis is characterized by inflammation of the lining of the joints and can cause patients chronic pain, loss of function and disability. It is estimated that rheumatoid arthritis affects roughly 1.5 million Americans and costs the U.S. economy nearly $40 billion a year.

24. Remsima® potentially can provide significantly more affordable treatments for the millions of Americans suffering from rheumatoid arthritis (as well as many other

chronic and debilitating diseases).

Celltrion has earned approvals for Remsima® in dozens of countries and is on course for U.S. approval in or about early 2015.

25. As a first step to introduce Remsima® into the U.S. market, Celltrion applied for and received Investigational New Drug ("IND") approval from multiple countries in 2010 to commence global clinical trials.

26. Beginning in March 2010, after successfully completing preclinical pharmacodynamic, pharmacokinetic, and toxicokinetic studies, Celltrion conducted global clinical trials. These trials involved 1,471 patients in 20 countries and 115 sites. Phase I clinical trials (completed in June 2012 and May 2013) and Phase III clinical trials (completed in July 2012 and July 2013) established that Remsima® was comparable in safety and efficacy to Remicade®. Celltrion relied on these global clinical trial results to secure approval to market Remsima® in multiple countries and regions. Celltrion will use these same clinical trial results to support its application for approval in the United States.

27. In March 2012, Celltrion submitted its formal approval application for Remsima® to Korea's MFDS. In July 2012, the MFDS approved Remsima®. Celltrion is now marketing Remsima® in Korea (and many other countries).

28. In March 2012, Celltrion submitted its Marketing Authorization Application to the EMA. On June 28, 2013, the EMA's Committee for Medicinal Products for Human Use issued a positive opinion for the approval of Remsima® in the European Union. In announcing its approval (on October 9, 2013), the EMA stated: "It is the first time that the biosimilar concept has been successfully applied to such a complex molecule, resulting in the recommended approval of a biosimilar version of Infliximab [Remicade®]." This

positive opinion allowed Celltrion to obtain marketing authorization approval from 28 European Union countries and three European Economic Area countries. Remsima® is the world's first biosimilar monoclonal antibody to receive approval from an advanced and developed nation's regulatory body. Celltrion is now marketing Remsima® pursuant to that authorization in several European countries.

29. As of this filing, 47 nations have approved Remsima®. In addition, Celltrion now has marketing approval applications for Remsima® pending in another 23 countries.

30. Bolstered by the positive acceptance that international regulatory bodies and healthcare professionals have given Remsima®, Celltrion is now focusing on obtaining FDA approval.

31. On July 10, 2013, Celltrion held a meeting with the FDA to receive in-depth data review of its full clinical study reports and advice regarding the need for additional studies, including design and analysis. Upon receiving guidance from the FDA, Celltrion submitted its IND application under section 505(i) of the Federal Food, Drug, and Cosmetic Act on October 2, 2013. The FDA accepted Celltrion's IND on November 18, 2013.

32. During its data review meeting, the FDA received Celltrion's Phase I and Phase III clinical trial results favorably, and the FDA recommended only that Celltrion perform a short follow-up clinical trial. Thus, on September 25, 2013, Celltrion applied for and received approval from Landesamt für Gesundheit und Soziales Berlin (State Office of Health and Social Affairs Berlin) to conduct a follow-up clinical study comparing Remsima® with EU-sourced Remicade® and U.S.-sourced Remicade®. This bridging study was commenced on October 7, 2013 and was successfully completed in March 2014.

33. Celltrion has scheduled a final meeting with FDA to discuss the format and

content of Celltrion's regulatory application. Through this meeting, Celltrion plans to finalize the specifics of its Biologic License Application ("BLA") for Remsima® and submit its BLA to the FDA shortly thereafter. Celltrion's marketing application for Remsima® is expected to follow the ordinary course in the FDA. Thus, Celltrion presently anticipates the FDA will approve Remsima® in or about the first quarter of 2015, which will include authorization to market Remsima® for the treatment of rheumatoid arthritis in conjunction with methotrexate.

Kennedy Has Sought to Improperly Extend the Enforceability Period of Its Patents.

34. On August 7, 2001, the U.S. Patent & Trademark Office issued U.S. Patent No. 6,270,766 (the "'766 patent") to Kennedy. The claims of the '766 patent are directed to methods of treating various inflammatory diseases, including rheumatoid arthritis by "co-administering" an anti-TNFα antibody and a common rheumatoid arthritis drug—methotrexate. In the '766 specification and during prosecution, Kennedy relied on examples disclosing "adjunctive" and "concomitant" co-administration to support the patentability of the '766 patent claims.

35. The '766 patent expired on October 8, 2012.

36. Celltrion is informed and believes that Kennedy has pursued additional U.S. patents to improperly extend the enforceability period of its co-administration invention to generate royalty income for Kennedy well beyond the life of the '766 patent. These additional patents include the '442, '537 and '120 patents.

37. The '442, '537 and '120 patents are continuations of the '766 patent. Therefore, they have the same specification as the '766 patent. Their claims are only slightly different

from the '766 patent claims.

38. The claims of the '442, '537 and '120 patents are directed to the same invention (or obvious variations of the same invention) that Kennedy claimed in the '766 patent. Like the '766 patent, the '442, '537 and '120 patents claim methods of treating patients suffering from rheumatoid arthritis by administering a combination of an anti-TNFα antibody and methotrexate. Like the examples given in the '766 specification and as confirmed by the '766 prosecution history, the claims of the '442, '537 and '120 patents recite that the co-administration is "adjunctive" and/or "concomitant." Thus, the claimed "adjunctive" and "concomitant" species of co-administration claimed in the '442, '537 and '120 patents are not separately patentable from the inventions claimed in the '766 patent.

39. Even though the claims of the '442, '537 and '120 patents cover the same subject matter as the '766 patent, Kennedy claimed a different—and later—priority date. The priority date for the '766 patent was October 8, 1992, the filing date of an earlier, abandoned patent application. Instead of carrying that same priority date over for its continuation patents, Kennedy claimed as the priority date the August 1, 1996 filing date of the '766 application. In doing this, Kennedy essentially extended the life of the base invention claimed in the '766 patent beyond the '766 patent's expiration. Indeed, with Kennedy publicly asserting that its '537 and '120 patents are enforceable until 2016 and that its '442 patent is enforceable until 2018, Kennedy has laid claim to an additional six years of lucrative royalties (barring a successful invalidity challenge to the patents).

40. Third parties have successfully challenged the validity of some claims of Kennedy's co-administration patents. In *AbbVie Inc., et al. v. The Mathilda and Terence Kennedy Institute of Rheumatology Trust*, S.D.N.Y. Civil Case No. 11-2541, this Court

invalidated claims 1-7, 13-14 and 17-20 of Kennedy's '442 patent for obviousness-type double patenting in view of the earlier '766 patent claims. The Court did not address the validity of the other '442 claims because those claims did not directly relate to AbbVie's product, Humira®, which is a fully human antibody. However, the inventions claimed in the unlitigated claims are identical to those recited in the claims this Court did invalidate, but for the fact that the invalidated claims cover all types of anti-TNFα antibodies (including fully human antibodies) while the unlitigated claims relate specifically to chimeric antibodies. But chimeric antibodies, including the cA2 molecule that is Remicade®, are specifically claimed in the earlier '766 patent. Therefore, a court should find the remaining claims invalid based on the same grounds stated in this Court's previous decision.

41. The Patent Office, in the merged proceedings in Ex Parte Reexamination 90/012,881 and Reissue 14/061,349, also rejected all claims of Kennedy's '442 patent on multiple grounds, including for obviousness-type double patenting in view of the '766 patent claims and additional prior art. The Patent Office, in Reissue 14/018,953, rejected all claims of Kennedy's '537 patent for similar reasons. In addition, the Patent Office determined that substantial new questions of patentability exist with respect to Kennedy's '120 patent claims in view of the '766 patent claims and certain prior art.

42. Despite this Court's and the Patent Office's findings regarding the invalidity or likely unpatentability of numerous claims of Kennedy's co-administration patents, Kennedy has continued to try to improperly extend its patent coverage beyond the expired term of the '766 patent. For example, Kennedy has instituted reissue proceedings for its '442 and '537 patents in an effort to try to salvage claims this Court and the Patent Office found to be invalid and/or likely unpatentable. But the claims Kennedy is litigating in the reissue

proceedings are not patentably different from those the Patent Office or this Court already has invalidated, and are not patentably different from the '766 patent claims.

43. Celltrion is informed and believes that Kennedy does not sell any products and exploits its patents solely by licensing them and enforcing them in court. Celltrion is informed and believes that Kennedy received millions of dollars in royalties during the life of the '766 patent, and has received millions more since the '766 patent expired. Kennedy has demonstrated it will continue to aggressively assert its co-administration patents beyond their legitimate term in order to maintain and even increase its lucrative royalty stream.

44. In all the post-grant proceedings before the Patent Office, Kennedy has left intact the majority of the '442, '537 and '120 patent claims.[6] Celltrion is informed and believes Kennedy will continue to assert at least some of those claims against Celltrion (and others) until they are finally determined to be invalid.

Kennedy Intends to Enforce Its U.S. Patents Against Celltrion.

45. Kennedy has sued to enforce and "vigorously" defend its co-administration patents against makers of anti-TNFα therapies in the United States. For example:

- In *Mathilda and Terence Kennedy Institute of Rheumatology Trust v. UCB, Inc.* (Civil Case No. 10-0650, D. Del.), Kennedy accused UCB of infringing the '766 patent. The '766 patent is the parent patent of the '442, '537 and '120 patents.
- In *Mathilda and Terence Kennedy Institute of Rheumatology Trust v. Amgen, Inc.*

[6] Kennedy has canceled several of the '537 dependent claims and has imported those limitations into the independent claims. Therefore, the claimed subject matter has not changed, even as to the amended claims.

(Civil Case No. 0-0805, D. Del.), Kennedy sued Amgen and Wyeth for infringing the '766 patent through sales of their Enbrel product.

- In *AbbVie Inc., et al. v. The Mathilda and Terence Kennedy Institute of Rheumatology Trust* (Civil Case No. 11-2541, S.D.N.Y.), Kennedy asserted counterclaims against AbbVie, Inc., seeking a declaration that the '442 patent is valid and that AbbVie's anti-TNF product Humira® is covered by the '442 patent. In 2012, the Court entered a final judgment of invalidity of all claims-at-issue. In the Court's findings of fact and conclusions of law, the Court stated that "[Kennedy] has a history of enforcing its patent rights against third parties." (Docket No. 25 at 6.)
- In *AbbVie Inc., et al. v. The Kennedy Trust for Rheumatology Research* (Civil Case No. 13-1358, S.D.N.Y.), Kennedy is defending claims against AbbVie that the '120 patent is invalid.

46. Kennedy also has asserted foreign counterparts to the '442, '537 and '120 patents against Celltrion and its marketing partners. In 2012, Celltrion, through its marketing partner Hospira U.K., Ltd., sued Kennedy in the United Kingdom's High Court of Justice, Chancery Division, Patents Court. In the action, Hospira (and Celltrion) asked the court to revoke the European counterpart patents to the '442, '537 and '120 patents. Kennedy responded by seeking a declaration that Inflectra® (Hospira's separate brand name for Celltrion's Remsima®) infringes the claims of those patents and by seeking an injunction against any future infringement. Kennedy publicly stated it was "defending the claim vigorously." On the eve of trial, in July 2013, Kennedy, in fear of losing its patents, contacted Celltrion to negotiate a licensing agreement and soon agreed to license its

patents to Celltrion. The court later dismissed the case upon mutual consent of the parties.

47. As part of the licensing discussions between Kennedy and Celltrion, Celltrion asked for a global license which would encompass Kennedy's corresponding U.S. and Canadian patents. Kennedy refused to include the U.S. and Canadian patents in the deal, leaving Celltrion exposed to patent infringement claims in those countries.

48. In fact, Kennedy has since filed claims for patent infringement in Canada against Celltrion. In that suit, Kennedy is seeking a declaration that Celltrion's biosimilar product infringes the Canadian counterpart to the '442 patent and an injunction against future infringement.

49. As part of discussions between the parties to the Canadian suit, Celltrion again asked Kennedy if it would license its U.S. patents to Celltrion as of Celltrion's anticipated U.S. approval date. Again, Kennedy refused to grant Celltrion the requested license.

50. Kennedy has publicly stated that one of its principal objectives is to "protect intellectual property created or acquired by the Trust." Kennedy also has declared that its "Future Plans" include: "Defending the Trust's patent portfolio and associated royalty income."

51. Kennedy has the resources to challenge Celltrion. Kennedy maintains a "Legal Expense Fund." The purpose of this fund "is to provide the means to enforce and protect patent rights and license terms, by arbitration or by litigation, and to meet the costs of current and future disputes concerning either the validity of the Trust's patents or the royalties payable to the Trust." As of September 30, 2012, the balance of Kennedy's Legal Expense Fund exceeded £16.3 million. During Kennedy's 2012 fiscal year, Kennedy spent more than £6.12 million on "Intellectual Property Protection."

52. In view of Kennedy's actions and statements, Celltrion has strong reason to believe Kennedy will assert the '442, '537 and '120 patents against Remsima® in the United States.

A Definite and Immediate Controversy Exists Between Kennedy and Celltrion Regarding the Invalidity of the '442, '537 and '120 Patents.

53. Celltrion is poised to introduce Remsima® into the U.S. market immediately upon the FDA's approval of Celltrion's BLA. Celltrion has successfully completed global Phase I and Phase III clinical trials demonstrating Remsima®'s safety and efficacy. The FDA accepted Celltrion's IND application for Remsima® on November 18, 2013. Celltrion completed a final pharmacokinetics study in healthy subjects in March 2014. Celltrion anticipates having its final pre-filing meeting with the FDA in April 2014 and expects to file its BLA shortly thereafter. In view of this progress, Celltrion anticipates receiving BLA approval for Remsima® in or about the first quarter of 2015.

54. The Remsima® product Celltrion will market in the United States is fixed and definite. Celltrion is now selling in Korea and several European countries the same formulation of Remsima® that Celltrion will set forth in its BLA. Forty-seven other countries have approved that formulation. The FDA has indicated that Celltrion's clinical trial results for the same Remsima® formulation are sufficient for an IND application filing, and the FDA has not raised any possibility of changing the formulation.

55. Celltrion has established a manufacturing, marketing and distribution infrastructure in anticipation of selling Remsima® in the United States. For example, Celltrion recently expanded one of its manufacturing plants, installed new equipment, and is proceeding with plans for a new manufacturing plant. It is Celltrion's goal to have several

months of supply of Remsima® on hand before its U.S. launch.

56. Celltrion Healthcare operates a U.S. office in Cambridge, Massachusetts. This office is responsible for, among other things, market research activities in the United States, developing greater understanding of the U.S. healthcare system, developing relationships with U.S. physicians; conducting surveys and market data analysis; developing U.S. marketing ties, and introducing physicians and other potential buyers and users to Remsima®. Celltrion expects this office to grow over time and provide additional services.

57. Celltrion has invested more than $112 million in out-of-pocket external costs, as well as significant internal manpower and other corporate resources, in developing Remsima® and in preparing to make the drug available to the millions of suffering Americans who could benefit from its use. Celltrion has endeavored to fully and timely comply with all FDA and other U.S. regulations and requirements so that it will be in a position to earn the fastest possible U.S. approval for Remsima®. In view of the significant resources and efforts Celltrion has invested in developing Remsima®, and in view of the potential market for Remsima® as suggested by Janssen's U.S. sales of Remicade® (published news reports indicate Q3 2013 U.S. sales of Remicade® exceeded $1.02 billion), any delay of Celltrion's market entry into the United States would have substantial and irreparable financial and other consequences for Celltrion.

58. Celltrion is aware of Kennedy's '442, '537 and '120 patents and Kennedy's assertions that these patents cover Remicade®. Kennedy has refused to grant Celltrion a license to these patents that would take effect when Celltrion requested. Celltrion also is aware of statements made and actions taken by Kennedy indicating that companies attempting to introduce Remicade® biosimilars will face patent litigation. Based on

Kennedy's prior conduct against third parties as well as against Celltrion and its marketing partners in the United Kingdom and Canada, and Kennedy's express refusal to grant Celltrion a license covering the United States that would take effect when Celltrion requested, Celltrion expects that Kennedy will try to block or negatively impact Celltrion's introduction of Remsima® into the U.S. market by asserting its '442, '537 and '120 patents.

59. Kennedy's assertions regarding its patent portfolio covering treatment of rheumatoid arthritis with anti-TNFα antibodies in combination with methotrexate, and its intent to block the introduction of anti-TNFα antibody products, have created uncertainties about Celltrion's Remsima® product and Celltrion's business. Celltrion is concerned that any attempt to introduce Remsima® into the United States before 2018 will result in Kennedy asserting claims for patent infringement damages and requests for preliminary and permanent injunctive relief. To remove these uncertainties and clear the way for Celltrion's U.S. launch of Remsima®, Celltrion seeks a declaration that the '442, '537 and '120 patents are invalid.

60. Under the totality of the circumstances, an actual controversy that is both immediate and real exists between Celltrion and Kennedy with respect to the validity of the '442, '537 and '120 patents.

First Cause of Action: Declaratory Judgment of Invalidity of the '442 Patent.

61. Celltrion realleges and incorporates by reference the allegations in paragraphs 1-60 above.

62. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Kennedy on the other hand, concerning whether the claims

of the '442 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

63. This controversy is amenable to specific relief through a decree of a conclusive character.

64. The claims of the '442 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

65. Celltrion is entitled to a judicial declaration that the claims of the '442 patent are invalid.

Second Cause of Action: Declaratory Judgment of Invalidity of the '537 Patent.

66. Celltrion realleges and incorporates by reference the allegations in paragraphs 1-65 above.

67. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Kennedy on the other hand, concerning whether the claims of the '537 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

68. This controversy is amenable to specific relief through a decree of a conclusive character.

69. The claims of the '537 patent are invalid for failure to comply with the statutory

prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

70. Celltrion is entitled to a judicial declaration that the claims of the '537 patent are invalid.

Third Cause of Action: Declaratory Judgment of Invalidity of the '120 Patent.

71. Celltrion realleges and incorporates by reference the allegations in paragraphs 1-70 above.

72. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Kennedy on the other hand, concerning whether the claims of the '120 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

73. This controversy is amenable to specific relief through a decree of a conclusive character.

74. The claims of the '120 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, and/or 112 and/or statutory or obviousness-type double patenting.

75. Celltrion is entitled to a judicial declaration that the claims of the '120 patent are invalid.

Prayer for Relief.

In view of the foregoing, Celltrion requests the Court to enter judgment in its favor and against Kennedy as follows:

a. Declaring that all claims of the '442 patent are invalid.

b. Declaring that all claims of the '537 patent are invalid.

c. Declaring that all claims of the '120 patent are invalid.

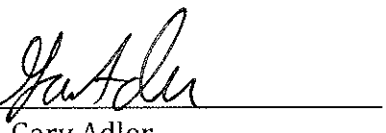
d. Declaring that this is an exceptional case in favor of Celltrion and awarding Celltrion its attorneys' fees under 35 U.S.C. § 285.

e. Awarding costs and expenses.

f. Awarding any and all such other relief as the Court determines to be just and proper.

Dated: March 31, 2014

Respectfully submitted,

By: 
Gary Adler

Bingham McCutchen LLP
Gary Adler
399 Park Avenue
New York, NY 10022-4689
Telephone: (212) 705-7000
Facsimile: (212) 752-5378
gary.adler@bingham.com

Bingham McCutchen LLP
Richard de Bodo (*pro hac vice* pending)
1601 Cloverfield Boulevard
Suite 2050 North
Santa Monica, CA 90404-4082
Telephone: (310) 907-1000
Facsimile: (310) 907-2000
rich.debodo@bingham.com

Attorneys for Plaintiffs Celltrion Healthcare Co., Ltd. and Celltrion, Inc.