United States District Court

District of Massachusetts

Celltrion Healthcare Co., Ltd., and Celltrion, Inc., Plaintiffs, vs. Janssen Biotech, Inc., Defendant.	Case No. 14-11613 **Celltrion's Complaint for Declaratory Judgment**

Introduction.

1. For the last 12 years, plaintiffs Celltrion Healthcare Co., Ltd. and Celltrion, Inc. (collectively "Celltrion") have, as their 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]

2. 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.

3. 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—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

[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.

approved under internationally accepted guidelines.

4. Remsima® is a biosimilar of the antibody drug Infliximab, which Defendant Janssen Biotech, Inc. ("Janssen") distributes under the trade name 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.

5. This case relates to Remsima® and its introduction into the United States. Janssen and its predecessors originally applied for patents relating to Remicade® in 1991, and obtained its first patent in 1997. Under U.S. law, Janssen's period of permissible patent protection should have already ended. However, Janssen and its predecessors are trying to improperly extend its monopoly after its initial patents expired. Janssen holds at least three U.S. patents—U.S. Patent Nos. 5,919,452 (the '452 patent), 6,284,471 (the '471 patent) and 7,223,396 (the '396 patent)—that will purportedly cover Remicade® beyond 2014. By this action, Celltrion seeks a declaratory judgment that Janssen's patents are invalid and unenforceable, thereby clearing the path for an affordable competitor to Janssen's Remicade® to enter the U.S. market.

6. 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 Janssen 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.

7. Remicade® represents billions of dollars in revenue to Janssen. Published reports indicate that worldwide sales of Remicade® exceeded $7.6 billion in 2012. Recognizing the value of its Remicade® market, Janssen and its affiliates, including its parent company Johnson & Johnson and its predecessor company Centocor, Inc. ("Centocor"), have aggressively sought patents relating to Remicade®. Centocor filed the first patent application related to Remicade® in 1991.

8. Celltrion is informed and believes that Janssen and its predecessors and affiliates have engaged in manipulative and deceptive practices before the U.S. Patent & Trademark Office to improperly extend the length of its patent monopoly for Remicade®, and to obtain patents the Patent Office never would have issued had it known all material facts. U.S. Patent Nos. 5,919,452 (the '452 patent), 6,284,471 (the '471 patent) and 7,223,396 (the '396 patent) are three of Janssen's patents relating to Remicade®. These patents are invalid and/or unenforceable.

9. Janssen has employed a variety of manipulative legal and other tactics to aggressively extend its multi-billion dollar patent monopoly over Remicade® throughout the world. Janssen and Johnson & Johnson have publicly asserted that Janssen's patent monopoly in the United States extends to 2018, even though the patent applications purporting to first disclose Remicade®-related inventions were filed more than 27 years before (in 1991). Janssen has touted the fact that it has provided Remicade® to patients for more than 20 years without competition. Celltrion reasonably believes Janssen will continue to fight any perceived challenge to its stranglehold over the U.S. market for

Remicade®. Celltrion is informed and believes that Janssen has refused Celltrion's request for a license to its U.S. Remicade®-related patents.

10. Celltrion's plan to launch Remsima® in the United States upon receiving approval in early 2015 and challenge Janssen's stranglehold over the market, and Janssen's scheme to extend its monopoly in the Remicade® market by asserting its follow-on wave of patents, place Celltrion and Janssen on an inevitable collision course. Thus, Celltrion now seeks a judicial declaration that, among other things, Janssen's '452, '471 and '396 patents are invalid and unenforceable.

11. 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.

12. Because Celltrion expects to face patent infringement allegations from Janssen, Celltrion wants to start the adjudicative process regarding the invalidity and unenforceability of Janssen's patents. This will enable Celltrion to immediately avail itself of the processes available in the federal judiciary to discover information relating to Janssen's patents, to learn Janssen's claim constructions and infringement contentions, and to present issues speedily for adjudication and test the validity and enforceability of Janssen's patents.

13. 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 Janssen'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.

14. Similarly, a decision by Celltrion to delay its launch of Remsima® would be harmful in several respects. It would harm Celltrion by depriving it of a return on its investment, significant revenues and profits arising from Remsima® sales, and other important business benefits. 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 also would harm the interests of individual Americans who could benefit from the use of Remsima®.

The Parties.

15. 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 an office for U.S. business operations in Cambridge, Massachusetts.

16. Celltrion is informed and believes that Janssen is a company organized and existing under the laws of Pennsylvania with its principal place of business in Horsham, Pennsylvania. Celltrion is informed and believes that Janssen is a wholly owned subsidiary

of Johnson & Johnson. Celltrion is informed and believes that Janssen manufactures, markets, and distributes Remicade® and other drug products. Celltrion is informed and believes that Janssen and New York University ("NYU") are the assignees of the '452, '471, and '396 patents. Celltrion is informed and believes that NYU has granted to Janssen an exclusive license to the '452, '471 and '396 patents and that Janssen therefore holds all substantial rights to the patents. Celltrion is informed and believes that Janssen intends to assert the '452, '471 and '396 patents to block Celltrion from introducing Remsima® into the U.S. market.

Jurisdiction and Venue.

17. 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).

18. This Court has personal jurisdiction over Janssen because, among other things, Janssen has continuous and systematic contacts with the State of Massachusetts, including marketing, distributing and selling products, including Remicade®, in Massachusetts.

19. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) because Janssen is subject to personal jurisdiction in the District of Massachusetts.

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.

20. 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.

21. 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.

22. 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®.

23. 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.

24. 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.[3] 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.

25. 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

[3] 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.

26. 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 a variety of diseases.

27. There is an urgent need for more affordable treatments for Americans suffering from rheumatoid arthritis, ulcerative colitis, Crohn's disease, ankylosing spondylitis, psoriatic arthritis, and psoriasis. 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. Crohn's disease is a chronic inflammatory condition of the gastrointestinal tract. Ulcerative colitis is a chronic disease of the large intestine, in

which the lining of the colon becomes inflamed and develops tiny open sores. It is estimated that Crohn's disease, ulcerative colitis, and other inflammatory bowel diseases cost the U.S. economy $1.84 billion a year. Psoriasis is a noncontagious, chronic, inflammatory, painful, disfiguring and disabling disease. Psoriasis affects approximately 7.5 million Americans and costs the U.S. economy more than $6 billion annually.

28. Remsima® potentially can provide significantly more affordable treatments for the millions of Americans suffering from these 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.

29. 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.

30. 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.

31. 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).

32. 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.

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

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

35. On July 10, 2013, in accordance with draft guidance provided by the FDA, 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.

36. 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. 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.

37. Celltrion has scheduled a final meeting with the 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.

Janssen Has Sought to Stifle Competition for Remicade® Through Improper and Inequitable Patent Prosecution Tactics.

38. Celltrion is informed and believes that Janssen's predecessor, Centocor, was founded in Philadelphia in or about 1979, that Centocor became a wholly owned subsidiary of Johnson & Johnson in or about 1999, that Centocor merged with Ortho Biotech Inc. to form Centocor Ortho Biotech Inc. in or about 2008, and that Centocor Ortho Biotech changed its name to Janssen Biotech, Inc. in or about June 2011.

39. Remicade® purportedly was developed in the United States by Centocor. The FDA granted its first approval for Remicade® in 1998, for the treatment of Crohn's disease. The FDA has since approved Remicade® for treating plaque psoriasis, ankylosing spondylitis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis.

40. Remicade® is based on the "cA2" molecule. Janssen's '452, '471 and '396 patents describe cA2 as a murine-human chimeric monoclonal antibody capable of binding to tumor necrosis factor alpha ("TNFα"). The cA2 molecule purportedly comprises the TNFα-binding variable regions of the mouse antibody designated A2 and the constant regions of a human IgG1 kappa immunoglobulin.

41. Janssen has sought to secure a lengthy monopoly over cA2-based drugs such as Remicade® by repeatedly patenting the same aspects of cA2 and its uses. Janssen first applied for patents describing Remicade® on March 18, 1991. Since then, Janssen has applied for dozens of patents that all claim the same purported invention covering cA2 and its uses, or obvious variations of that purported invention. For example, Janssen has obtained at least six patents with claims directed to the same anti-TNFα antibodies (and that all purportedly cover cA2), including patents the Patent Office granted as recently as 2008 arising from applications the Patent Office received in 2007. The '471 patent is one of these patents.

42. The Patent Office issued the '471 patent on September 4, 2001. The patent is entitled "Anti-TNFa Antibodies And Assays Employing Anti-TNFa Antibodies." The '471 patent identifies Junming Le, Jan Vilcek, Peter Dadonna, John Ghrayeb, David Knight and Scott A. Siegel as the inventors. Celltrion is informed and believes that Janssen and NYU are the assignees of the '471 patent. Celltrion is also informed and believes that Janssen is the holder of all substantial rights to the patent under an exclusive license from NYU. A copy of the '471 patent is attached as Exhibit A.

43. The Patent Office issued the '452 patent on July 6, 1999. The patent is entitled "Methods of Treating TNFα-Mediated Disease Using Chimeric Anti-TNF Antibodies." The

'452 patent identifies Junming Le, Jan Vilcek, Peter Dadonna, John Ghrayeb, David Knight and Scott A. Siegal as the inventors. Celltrion is informed and believes that Janssen and NYU are the assignees of the '452 patent. Celltrion is also informed and believes that Janssen is the holder of all substantial rights to the patent under an exclusive license from NYU. A copy of the '452 patent is attached as Exhibit B.

44. The Patent Office issued the '396 patent on May 29, 2007. The patent is entitled "Methods of Treatment of Fistulas in Crohn's Disease with Anti-TNF Antibodies." The '396 patent identifies Junming Le, Jan Vilcek, Peter Dadonna, John Ghrayeb, David Knight and Scott Siegel as the inventors. Celltrion is informed and believes that Janssen and NYU are the assignees of the '396 patent. Celltrion is also informed and believes that Janssen is the holder of all substantial rights to the patent under an exclusive license from NYU. A copy of the '396 patent is attached as Exhibit C.

45. Celltrion is informed and believes that Janssen presently claims to have right, title and interest in the '452, '471 and '396 patents, that Janssen has the exclusive right to enforce those patents, and that Janssen claims those patents cover Remicade®.

46. Janssen improperly has attempted to obtain and extend patent protection for Remicade® in numerous ways. For example, Celltrion is informed and believes Janssen purposefully delayed prosecution of the '471 patent to improperly extend the term of that patent. On February 4, 1994, Janssen filed the original application from which the '471 patent issued, U.S. Patent Application No. 08/192,093, and then stretched out the prosecution of that application for more than seven years.

47. During prosecution, the '471 applicants amended the claims seven times. The original claims of Application No. 08/192,093 did not specifically claim the cA2 molecule.

The applicants added a single claim directed to cA2 by Amendment on December 27, 1994, but then cancelled it in a December 1, 2000 Amendment. Except for one claim directed to an immunoassay method for detecting human TNF, the applicants first proposed the claims that issued in the '471 patent, including the cA2-specific claims, in 1997, after the Patent Office issued U.S. Patent No. 5,656,272 (the "'272 patent"). The applicants snuck in the cA2-specific claims late in the prosecution of the '471 patent even though the parent application (08/013,413, filed in 1993) already included claims reciting the cA2 molecule and the issued '272 patent claimed methods of using the cA2 molecule.

48. The '471 applicants' unexplained and unreasonable delays in prosecuting the '471 application resulted in a significant delay in patent issuance, and thus a later expiration date. According to Janssen's public statements, the '471 patent will not expire until 2018—24 years after the filing of the '471 application and 27 years after the filing of the priority application.

49. In addition, Janssen breached its duty of candor and engaged in inequitable conduct before the Patent Office to obtain its '396 patent. In February 1994, Janssen filed two separate patent applications with claims directed to the use of anti-TNF antibodies, including cA2, in Crohn's disease. The Patent Office examiner cited a 1993 reference by Bert Derkx as relevant to these claims. Celltrion is informed and believes the examiner did not rely on the Derkx Reference to reject the claims of either application because those applications claimed priority to 1991 (before the publication of Derkx).

50. More than eight years after the filing of the February 1994 applications, and more than five years after those applications issued, Janssen filed the application that issued as the '396 patent (Application No. 10/319,011—"'011 Application"). The '011

Application, like the two earlier applications discussed above, sought claims directed to the use of anti-TNF antibodies, including cA2, in Crohn's disease. In support of these claims, the applicants relied on a portion of the specification that is nearly identical to the disclosure of the Derkx Reference. But unlike the February 1994 applications, in the '011 Application Janssen deleted its claim to priority to any prior application having a filing date before October 1994. Thus, the Derkx Reference was prior art to the '011 Application. The applicants knew Derkx was a material reference because the Patent Office had cited Derkx against similar claims years earlier and the applicants had relied on information first reported in Derkx to support their claims. Yet, the applicants intentionally failed to disclose Derkx to the examiner. Celltrion is informed and believes that Janssen's intentional failure to disclose Derkx was part of an effort to deceive the Patent Office as part of a scheme to obtain further patent protection for Remicade®.

Janssen Has Aggressively Sought to Protect Its Remicade® Monopoly by Asserting Legal Challenges Against Competing Products, Including Remsima®.

51. Over the last decade, Janssen has aggressively sought to protect its monopoly of the multi-billion dollar Remicade® market. Janssen has confronted and engaged its perceived competitive threats on many fronts.

52. For example, Janssen has filed numerous U.S. patent infringement suits relating to Remicade®, including:

- *Centocor Ortho Biotech, Inc. et al. v. Abbott Laboratories, et al.* (Civil Case No. 9-0389, E.D. Tex., filed December 28, 2009) (complaint for continuing damages relating to alleged infringement of Janssen's patents by Abbott's anti-TNFα

antibody product, Humira®);

- *Centocor Ortho Biotech, Inc. v. Genentech, Inc., et al.* (Civil Case No. 8-3573, C.D. Cal., filed May 30, 2008) (asserting invalidity and unenforceability of licensed patents covering Remicade®);
- *Centocor Ortho Biotech, Inc. et al. v. Abbott Laboratories, et al*. (Civil Case No. 7-0139, E.D. Tex., filed April 16, 2007) (alleging patent infringement by Abbott's Humira® product, which is a competing anti-TNFα antibody product approved for the treatment of similar conditions as Remicade®); and
- *The Rockefeller University, et al. v. Centocor, Inc., et al*. (Civil Case No. 4-0168, E.D. Tex., filed April 28, 2004) (defending Remicade® against infringement claims).

53. More recently, Janssen has taken action in many countries in an attempt to disrupt and delay the introduction of Remsima®. For example, in the Canadian suit styled *The Kennedy Trust for Rheumatology Research, et al. v. Celltrion, Inc*., *et al.*, Janssen, as a licensee of a patent held by Kennedy, is seeking a declaration that Celltrion's Remsima® would infringe a Kennedy patent purporting to cover uses of Remicade®. Janssen is seeking a permanent injunction restraining Celltrion from manufacturing or selling any product purportedly infringing on the Kennedy patent.

54. Celltrion is informed that Janssen has refused to grant Celltrion a license to its U.S. patents and has even refused to discuss the subject of a possible license with Celltrion. This further confirms Janssen's intent to assert its patents against Remsima® to prevent Celltrion's entry in the U.S. market.

55. In numerous countries (*e.g*., Argentina, Australia, Bolivia, Brazil Canada, Chile,

India, Korea, the Philippines, South Africa, and Uruguay), Janssen filed oppositions to Celltrion's application for registration of the trademark "Remsima." Janssen initiated trademark opposition and invalidation proceedings in Korea (all of which were decided in Celltrion's favor) and Paraguay.

56. In Mexico, Janssen has argued to the Comisión Federal para la Protección contra Riesgos Sanitarios that it should not approve Celltrion's Remsima® due to data exclusivity, regardless of the fact that there are no such regulations in Mexico. Celltrion is informed and believes that Janssen's contentions are meritless and that Janssen asserted them anyway knowing that ***any*** challenge, no matter how frivolous, would automatically result in a stay of a pending marketing application. Janssen's obstructionist tactics caused the Mexican authorities to stay approval of Celltrion's application, which has resulted in a delay of Celltrion's launch of Remsima® in Mexico.

57. In Peru, where the authorities already had granted marketing authorization for Remsima®, Johnson & Johnson petitioned the court to suspend the marketing license, arguing that Remsima® was hastily approved without the establishment of any biosimilar approval guidelines, and that Celltrion's application raised serious health concerns. In response to Johnson & Johnson's maneuver, the Superior Court of Lima suspended Remsima®.

58. In the United Kingdom, Celltrion, through its marketing partner Hospira U.K., Ltd., brought suit in the United Kingdom's High Court of Justice, Chancery Division, Patents Court against The Mathilda and Terence Kennedy Institute of Rheumatology Trust, which holds title to certain patents potentially covering Remsima®. In this action, Hospira asked the court to revoke certain patents allegedly relating to uses of cA2 (including Remicade®

and Remsima®). 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. As part of licensing discussions, Celltrion and Kennedy discussed the possibility of Kennedy giving Celltrion a global license, including licenses to Kennedy's corresponding U.S. and Canadian patents. Celltrion is informed that Janssen, Kennedy's non-exclusive licensee, demanded that Kennedy not grant Celltrion a license to any U.S. or Canadian patents. As a result, Kennedy refused to include the U.S. and Canadian patents in the deal. Thereafter, Kennedy and Janssen asserted infringement claims against Celltrion in Canadian proceedings. Celltrion is informed that, as part of the Canadian proceedings, Janssen again refused Celltrion's request that it grant Celltrion a license to Janssen's U.S. patents and refused to even discuss the possibility of licensing Celltrion its U.S. patents (*see*, *supra*, ¶¶ 53-54).

59. In the United States, on January 7, 2014, Johnson & Johnson submitted a Citizen's Petition asking the FDA "to require biosimilars to bear nonproprietary names that are similar to, but not the same as, those of their reference products or of other biosimilars." In its petition, Johnson & Johnson specifically mentions Remicade® as one of the biologic drugs in its biologics portfolio. Johnson & Johnson argues that nonproprietary names of biosimilars should differ in order to simplify safety monitoring post-approval and to avoid confusion among pharmacists, doctors, and patients.

60. Johnson & Johnson has asserted and has been quoted in news reports that Remicade® will enjoy U.S. patent protection until 2018, and that the owners of patents covering Remicade® (*i.e.,* Janssen) may initiate patent infringement cases against entities

that try to introduce Remicade® biosimilars (*i.e.,* Celltrion).

A Definite and Immediate Controversy Exists Between Celltrion and Janssen Regarding the Invalidity and Enforceability of the '452, '471 and '396 Patents.

61. 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 will have 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.

62. 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.

63. 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.

64. 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.

65. 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.

66. Celltrion is aware of Janssen's '452, '471 and '396 patents and Janssen's assertions that these patents cover Remicade®. Janssen has refused to grant Celltrion a license to these patents and other U.S. patents related to Remicade®. Celltrion also is aware of statements made by Janssen's parent company, Johnson & Johnson, that the patents purportedly covering Remicade® will not expire until 2018, and of reports that companies attempting to introduce Remicade® biosimilars will face patent litigation.

Celltrion also is aware of the many steps Janssen and Johnson & Johnson have taken in all areas of the world to try to block or delay Celltrion's introduction of Remsima®.

67. Janssen's assertions regarding its patent monopoly and its global activities aimed at blocking the introduction of Remsima® have created uncertainties about Celltrion's Remsima® product and its business operations. Celltrion fears that any attempt to introduce Remsima® into the United States before 2018 will result in Janssen asserting claims for patent infringement damages and for preliminary and permanent injunctive relief. To remove these uncertainties and clear the way for Celltrion's introduction of Remsima® into the U.S. market, Celltrion seeks a declaration that the '452, '471 and '396 patents are invalid and unenforceable. Celltrion also seeks a declaration that the '452 patent expires on August 12, 2014.

68. Under the totality of the circumstances, an actual controversy that is both immediate and real exists between Celltrion and Janssen with respect to the validity and enforceability of the '452, '471 and '396 patents.

First Cause of Action:
Declaratory Judgment of Invalidity of the '452 Patent.

69. Celltrion repeats and realleges, as if fully set forth at this point, the allegations contained in all the preceding paragraphs.

70. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

71. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Janssen on the other hand, concerning whether the claims of the '452 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.

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

73. The claims of the '452 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.

74. Celltrion is entitled to a judicial declaration that the claims of the '452 patent are invalid.

Second Cause of Action:
Declaratory Judgment of Expiration of the '452 Patent.

75. Celltrion repeats and realleges, as if fully set forth at this point, the allegations contained in all the preceding paragraphs.

76. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

77. The cover sheet of the '452 patent indicates the patent is subject to a terminal disclaimer. In the Notice of Allowance of the '452 patent, the U.S. Patent & Trademark Office stated that the pending rejection "under the judicially created doctrine of obviousness-type double patenting … over the claims of U.S. Patent No. 5,656,272 or 5,698,195 is withdrawn in view of the terminal disclaimer." An interview summary dated October 26, 1998 indicates that the "[t]erminal disclaimer will be faxed by end of day." The on-line electronic Patent Office record of transactions that took place during prosecution of

the '452 patent indicates that a terminal disclaimer was filed on October 26, 1998 and was approved by the Patent Office on November 3, 1998.

78. Celltrion is informed and believes that the '272 patent expires on August 12, 2014, and that the '195 patent expires on December 16, 2014.

79. Celltrion is informed and believes that the official file history of the '452 patent, on file with the U.S. Patent & Trademark Office, does not contain a copy of the terminal disclaimer. Celltrion requested a copy of the terminal disclaimer from the U.S. Patent & Trademark Office, and the Office responded it could not find any such document. A copy of that request and the Patent and Trademark Office's response is attached as Exhibit D.

80. Celltrion is informed and believes that the term of the '452 patent is shortened to the statutory term of the '272 and/or '195 patents, and therefore, expires on August 12, 2014.

81. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Janssen on the other hand, concerning whether the claims of the '452 patent are enforceable beyond the expiration dates of the '272 and '195 patents.

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

83. The claims of the '452 patent are subject to a terminal disclaimer listing both the '272 and '195 patents, and are not enforceable beyond August 12, 2014.

84. Celltrion is entitled to a judicial declaration that the '452 patent expires on August 12, 2014.

Third Cause of Action:
Declaratory Judgment of Invalidity of the '471 Patent.

85. Celltrion repeats and realleges, as if fully set forth at this point, the allegations contained in all the preceding paragraphs.

86. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

87. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Janssen on the other hand, concerning whether the claims of the '471 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.

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

89. The claims of the '471 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.

90. Celltrion is entitled to a judicial declaration that the claims of the '471 patent are invalid.

Fourth Cause of Action:
Declaratory Judgment of Unenforceability of the '471 Patent.

91. Celltrion repeats and realleges, as if fully set forth at this point, the allegations contained in all the preceding paragraphs.

92. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

93. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Janssen on the other hand, concerning whether the claims of the '471 patent are enforceable under the doctrine of prosecution laches.

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

95. The '471 patent is unenforceable under the doctrine of prosecution laches. The '471 patent issued after an unreasonable and unexplained delay in the prosecution of the application that led to the issuance of the '471 patent (and related applications).

96. Celltrion is entitled to a declaration that the '471 patent is unenforceable under the doctrine of prosecution laches.

Fifth Cause of Action:
Declaratory Judgment of Invalidity of the '396 Patent.

97. Celltrion repeats and realleges, as if fully set forth at this point, the allegations contained in all the preceding paragraphs.

98. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

99. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Janssen on the other hand, concerning whether the claims of the '396 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.

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

101. The claims of the '396 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.

102. Celltrion is entitled to a judicial declaration that the claims of the '396 patent are invalid.

Sixth Cause of Action:
Declaratory Judgment of Unenforceability of the '396 Patent.

103. Celltrion repeats and realleges, as if fully set forth at this point, the allegations contained in all the preceding paragraphs.

104. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

105. There is a real, immediate, substantial, and justiciable controversy between Celltrion, on the one hand, and Janssen on the other hand, concerning whether the claims of the '396 patent are unenforceable due to inequitable conduct before the U.S. Patent Office.

106. On July 17, 1993, *The Lancet* (Vol. 342:173-74) published an article by Bert Derkx et al., entitled "Tumour-necrosis-factor antibody treatment in Crohn's disease." The Derkx Reference describes treating a 12-year-old patient suffering from Crohn's disease with anti-TNFα antibody cA2 supplied by Centocor (*i.e.,* Janssen). The article discloses the dosing regimen and administration specifics, and reports that the patient receiving cA2 treatment improved dramatically, including a reduction of lesion and abscess symptoms

and Crohn's disease activity scores, with no side effects.

Janssen knew about the Derkx Reference before it applied for the '396 patent.

107. The Derkx Reference expressly states that Centocor supplied the cA2 antibody used in the study. This indicates that Centocor (the employer of the named inventors and predecessor of Janssen) knew of the study at or about the time of its publication.

108. Janssen referred to the Derkx Reference in two patent applications it filed in February 1994. On February 4, 1994, Janssen filed Application No. 08/192,102 (the "'102 Application"). The '102 Application ultimately issued in 1997 as U.S. Patent No. 5,656,272, which claims priority to U.S. Application No. 07/670,827 (the "'827 Application," filed on March 18, 1991). In the '102 Application, Janssen presented "Example XXI," which disclosed test results for a patient receiving cA2 treatment. The content of Example XXI appears to be identical to that of the Derkx Reference:

Disclosures in Example XXI	Disclosures in Derkx
▪ Concerns a female patient with a history of Crohn's disease	▪ Discusses a female patient with a history of Crohn's disease
▪ Since age 12, the patient had been treated daily with mesalazine, prednisone, azathioprine	▪ Since age 12, the patient previously had been treated with mesalazine, prednisone and azathioprine
▪ The patient had severe inflammation and ulcerations of her colon	▪ The patient suffered from severe inflammation and lesions in her colon
▪ The patient was infused with 10 mg/kg cA2	▪ The patient was infused twice with 10 mg/kg cA2 supplied by Centocor
▪ The patient had a complete remission (including of her abscess and lesion symptoms)	▪ Thereafter, the patient had a complete remission involving a lessening of her abscess and lesion symptoms
▪ By the time of her second cA2 administration, the patient's Crohn's index went from 311 to 105 and her pediatric score went from 77.5 to 15	▪ By the time of her second cA2 infusion, the patient's Crohn's index went from 311 to 105 and her pediatric score went from 77.5 to 15

109. Janssen also included Example XXI in Application No. 08/192,861 (the "'861 Application"), which Janssen also filed on February 4, 1994. The '861 Application ultimately issued in 1999 as the '452 patent. Like the '102 Application, the '861 Application claimed priority to the '827 Application (with the March 18, 1991 priority date).

110. The Patent Office cited the Derkx Reference during the prosecution of both the '102 and '861 applications. The first citation occurred during the '102 Application prosecution. In a December 20, 1995 Non-Final Rejection of the '102 Application's claims, U.S. Patent Examiner Nisbet cited the Derkx Reference. At the time, the claims pending in the '102 Application were directed to methods of treating Crohn's disease by administering

"an effective TNF-inhibiting amount of anti-TNF chimeric antibody, wherein said anti-TNF chimeric antibody comprises a non-human variable region or a TNF-binding portion thereof and a human constant region." Other independent claims recited an antibody that competitively inhibits the binding of TNF to A2 or cA2.

111. In a January 2, 1996 Non-Final Rejection of the '861 Application claims, Examiner Nisbet again cited the Derkx Reference. At the time of the rejection, the '861 Application claims were directed to methods of treating Crohn's disease comprising administering an amount of an anti-TNF chimeric antibody, including cA2.

112. Celltrion is informed and believes that Examiner Nesbit did not rely on Derkx to reject either the '102 Application or '861 Application claims because both of those applications claimed an earlier priority date (March 18, 1991) than Derkx's publication date (July 17, 1993).

Janssen failed to disclose the Derkx Reference to the Patent Office during the '396 patent prosecution.

113. On December 12, 2002 (years after the Patent Office issued the '452 and '272 patents), the named inventors of the '396 patent (Junming Le, Jan Vilcek, Peter Dadonna, John Ghrayeb, David Knight and Scott Siegel), patent prosecution counsel (including, Hamilton, Brook, Smith & Reynolds and its lawyers), and other persons, companies, and/or firms associated with the filing and the prosecution of the '396 patent (collectively "'396 applicants"), filed U.S. Patent Application No. 10/319,011 (the "'011 Application"). The '396 Patent issued from the '011 Application.

114. The '011 Application, as originally filed, claimed priority to a dozen earlier-filed Janssen applications, including the '827 Application, filed on March 18, 1991. However, on

September 28, 2006, in response to the examiner's invitation to clarify the claimed priority, the '396 applicants deleted priority claims to the '827 Application and the many other early applications. Instead, the '396 applicants claimed priority to Application No. 08/324,799 (the "'799 Application"), filed on October 18, 1994. The '396 applicants did this despite the Examiner's opinion that it may have been entitled to an earlier priority date—February 4, 1994, the filing date of the '102 and '861 Applications. Thus, the earliest priority date claimed for the '396 patent (as issued) is October 18, 1994.

115. By virtue of its claimed priority date of October 18, 1994, the Derkx Reference was prior art to the '011 Application.

116. Even though the Derkx Reference was prior art to the '011 Application, the '396 applicants never disclosed the reference to the Patent Office. Throughout 2003, even though the prosecution of the '011 Application was relatively dormant, the '396 applicants submitted numerous references to the Patent Office. For example, on August 12, 2003, they submitted an Information Disclosure Statement ("IDS") noting that copies of cited references were entered in prior applications 09/756,398, 08/943,852 and 08/192,093. The '396 applicants asked the Patent Office to consider 21 other pending applications filed by the applicants and further attached 10 pages of additional disclosures that identified 65 patents and 101 publications. The '396 applicants did not include the Derkx Reference in this IDS disclosure.

117. On August 16, 2006, Examiner Gambel conducted an interview with the '396 applicants. During the interview, the '396 applicants discussed with the examiner amending the claims to inhibit TNFα in Crohn's patients with fistulas. There is no record that the '396 applicants discussed the Derkx Reference during the interview.

118. After the interview, on September 28, 2006, the '396 applicants submitted amendments and remarks. The '396 applicants also submitted amended claims that included the claims that eventually issued in the '396 patent. With their September 2006 amendment and remarks, the '396 applicants submitted another IDS. In this IDS, the applicants asked the Patent Office to consider another 18 published and non-published pending applications. The IDS also asked the Patent Office to consider 10 additional patents, all assigned to Centocor. The IDS did not disclose Derkx.

Janssen knew of the materiality of the Derkx Reference during the '396 patent prosecution.

119. When the '396 applicants submitted amended claims on September 28, 2006, the '396 applicants expressly relied upon Example XXI—which, as discussed above, also was present in the earlier '102 and '861 Application specifications (the '396 patent is not related to the '102 and '861 applications because the '396 applicants deleted the priority claim to those applications). As previously discussed, the content of Example XXI is essentially identical to that of Derkx. Given the fact that the '396 applicants relied on disclosures that are nearly identical to the disclosures of Derkx in support of claims in their own application, the '396 applicants had to consider Derkx a material reference no later than September 28, 2006.

120. Given their knowledge of the Derkx Reference by early 1996, the '396 applicants also would have realized the materiality of the reference in view of an action taken by the Patent Office on May 9, 2006. On that day, Examiner Gambel issued a Non-Final Office Action rejecting all then-pending claims of the '011 Application. Among other grounds, Examiner Gambel found it was obvious to combine a "Schreiber" reference with other

references to reach the claimed invention. He noted that Schreiber taught the use of anti-TNF agents in the treatment of inflammatory bowel disease, including Crohn's disease and fistulating disease. Although Examiner Gambel felt Schreiber did not disclose the characteristics of the cA2 anti-TNF antibody as well as the dosing regimens and combination therapies recited in the '011 Application, he felt it would have been obvious. Examiner Gambel wrote:

> "A person of ordinary skill in the art would have recognized that treating various inflammatory conditions with anti-TNF antibodies as discussed by the prior art references would be appropriate for a number of inflammatory conditions, including chronic inflammatory bowel diseases associated with pro-inflammatory TNF at the time the invention was made."

121. Celltrion is informed and believes that Examiner Gambel did not know of the Derkx Reference at the time he issued the May 9, 2006 Non-Final Office Action. But the Derkx Reference would have fully supported Examiner Gambel's argument that the invention claimed by the '011 Application was unpatentable, either in view of Derkx by itself or in combination, for example, with Schreiber. Thus, the substance of Examiner Gambel's May 9, 2006 rejections evidences the materiality of the Derkx Reference to the prosecution of the '011 Application.

Janssen's failure to disclose the Derkx Reference to the Patent Office during the '396 prosecution constitutes inequitable conduct.

122. Celltrion is informed and believes the '396 applicants knew of the Derkx Reference and its materiality during the '396 prosecution in view of at least these facts:

- The Patent Office made it clear in its May 9, 2006 Non-Final Rejection of the '011 Application claims that the information disclosed in the Derkx Reference, had it been disclosed to the Patent Office, would be material to the '011

Application.

- The ‘011 Application claims that the Patent Office rejected on May 9, 2006 were similar to those the Patent Office rejected in the ‘102 and ‘861 Applications, and Examiner Nisbet cited the Derkx Reference as material during the prior ‘102 and ‘861 application prosecutions.
- The Derkx Reference expressly states that Centocor supplied the cA2 antibody used in the study, indicating Centocor knew about the study.
- The ‘011, ‘102 and ‘861 applications all list the same inventors. The named inventors therefore knew of Derkx because it was cited in connection with the ‘102 and ‘861 applications.
- The same law firm—Hamilton, Brooks, Smith & Reynolds—was responsible for the prosecution of the ‘011, ‘102 and ‘861 applications. Attorney Deidre Sanders prosecuted the ‘011 Application, and was involved in prosecuting the ‘102 application. Additionally, David Brook was granted power of attorney in connection with the ‘861 Application prosecution and also was involved in the ‘011 Application prosecution. The attorneys involved with the ‘011 Application therefore knew of Derkx because it was cited in connection with the ‘102 and ‘861 applications.
- For support of the issued claims, the ‘396 applicants relied on ‘011 Application specification disclosures that appear to be lifted directly from the Derkx Reference.
- The applicants, having likely learned of the Derkx Reference in 1993, included its results at Example XXI in the very next continuation-in-part application

they filed.

123. The only reasonable inference to be drawn from the facts that the '396 applicants knew about the Derkx Reference since as early as 1993 and no later than early 1996, knew of its materiality, knew it was not cumulative to the art cited during prosecution of the '396 patent, and still did not disclose it to Examiner Gambel despite the clear overlap in subject matter, is that such actions were intentional and done for the purpose of deceiving the Patent Office in order to obtain a later priority date, and thus, an improperly extended patent term.

124. Throughout the prosecution of the '011 Application, the '396 applicants had numerous opportunities to disclose the Derkx Reference, but chose not to. Celltrion is informed and believes that the '396 applicants instead bombarded the Patent Office with other, less material references to create the impression of full disclosure. The '396 applicants also relied on the fact that Examiner Gambel (who Celltrion is informed and believes was unaware of Derkx) was responsible for the '011 Application while Examiner Nesbit (who did know about Derkx) was responsible for the '102 and '861 applications.

125. The asserted priority date for the '396 patent is October 18, 1994, the filing date of U.S. Patent Application No. 08/324,799. The asserted priority date is more than one year after the publication of Derkx, and more than three years after the asserted priority dates of the '102 and '861 applications, which also recite the Derkx results as Example XXI.

126. Celltrion is informed and believes that Janssen improperly extended the term of the '396 patent to 2016 by claiming a later priority date than that claimed by the '102 and '861 applications, and by intentionally concealing the Derkx Reference from the Patent Office.

127. This controversy regarding the unenforceability of the '396 patent due to inequitable conduct before the U.S. Patent Office is amenable to specific relief through a decree of a conclusive character.

128. Janssen controlled and/or had knowledge of the prosecution of the application that led to the issuance of the '396 patent (and related applications) and is accountable for the failure to disclose the material Derkx Reference to the Patent Office.

129. With knowledge of the Derkx Reference and knowing that the reference was material, and while under a duty of candor to the Patent Office, Janssen knowingly and deliberately deceived the Patent Office in material ways, including by not disclosing the Derkx Reference to the Patent Office.

130. Janssen's conduct constitutes inequitable conduct. Celltrion is informed and believes that the Patent Office would not have issued the '396 patent had Janssen disclosed the Derkx Reference during prosecution.

131. Celltrion seeks a declaratory judgment that the '396 patent is unenforceable due to Janssen's inequitable conduct.

Prayer for Relief.

In view of the foregoing, Celltrion prays that the Court enter judgment in its favor and against Janssen as follows:

a. Declaring that all claims of the '452 patent are invalid.

b. Declaring that the '452 patent expires on August 12, 2014.

c. Declaring that all claims of the '471 patent are invalid.

d. Declaring that all claims of the '471 patent are unenforceable.

e. Declaring that all claims of the '396 patent are invalid.

f. Declaring that all claims of the '396 patent are unenforceable.

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

h. Awarding costs and expenses.

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

Dated: March 31, 2014

Respectfully submitted,

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

By their attorneys,

/s/ Joshua M. Dalton

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