

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent of: Fraunhofer et al.  
U.S. Patent No.: 9,085,619  
Issue Date: July 21, 2015  
Appl. Serial No.: 14/506,576  
Filing Date: October 3, 2014  
Title: ANTI-TNF ANTIBODY FORMULATIONS

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P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION OF DAVID D. SHERRY, M.D.**

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I, David D. Sherry, M.D., declare that:

**I. QUALIFICATIONS AND BACKGROUND INFORMATION**

1. I received my M.D. from Texas Tech University School of Medicine in 1977. I completed my internship (1978), and then my residency (1980) in pediatrics at Duke University Medical Center. I afterwards had a fellowship in pediatric rheumatology at the University of British Columbia from 1980 through 1982.

2. From 1982 to 1984, I was Assistant Clinical Professor of Pediatrics at the University of Southern California while practicing in the Division of Rheumatology and Rehabilitation at the Childrens Hospital of Los Angeles. From 1984 to 2002, I was Assistant Professor of Pediatrics, then Associate Professor and Professor at the University of Washington in Seattle. During that time in Seattle, I practiced and then was also Director of Pediatric Rheumatology at the Children's Hospital and Regional Medical Center in Seattle.

3. Since 2002, I have been Professor of Pediatrics at The Children's Hospital of Philadelphia, Perelman School of Medicine at the University of Pennsylvania. I have also practiced as the Chief Rheumatology Section during that time.

4. I sat for my medical boards in 1979, and I received certifications in pediatrics in 1981, and in pediatric rheumatology in 1992, and again in 1999 and

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2006. I am currently licensed to practice medicine in the state of Pennsylvania. I am currently a Fellow of the American College of Rheumatology.

5. My practice focuses on the treatment of children with rheumatic and inflammatory diseases, including juvenile idiopathic arthritis and its subtypes. In the course of treating these diseases, I regularly prescribed treatments such as methotrexate and anti-TNF $\alpha$  biologics such as Remicade®, Enbrel®, Humira®, and others.

6. In addition to patients with rheumatic illnesses, I have had a long time interest in children with various forms of amplified pain, thereby making pain and the experience thereof a clinical and research interest. This specifically has included injection pain. Likewise it includes the emotional impact of pain on the child and family albeit mostly in those with chronic pain.

7. A copy of my *curriculum vitae* is attached as Exhibit A to this Declaration.

## **II. COMPENSATION**

8. I have been retained in this matter by Rothwell, Figg, Ernst & Manbeck, P.C. (“Rothwell Figg”). I am being compensated at my customary rate of \$650 per hour for my work in this matter. I do not have any personal or financial stake or interest in the outcome of the Petition for *Inter Partes* Review or any

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related action. My compensation in no way depends upon my testimony or the outcome of the Petition for *Inter Partes* Review.

9. I have been advised that Rothwell Figg represents Coherus Biosciences Inc. (“Coherus” or “Petitioner”) and that AbbVie Biotechnologies Ltd. (“AbbVie” or “Patent Owner”) owns U.S. Patent No. 9,085,619 (“the ’619 patent”). I have no personal or financial stake or interest in Coherus, AbbVie, or the ’619 patent.

### **III. MATERIALS CONSIDERED**

10. In preparing this declaration, I have considered my own knowledge and experience, including my work and experience as a practicing doctor in the field rheumatology and my experience prescribing Humira® and other treatments for juvenile idiopathic arthritis. In addition to the materials cited herein, I have read the ’619 patent. A list of documents I have considered is attached as Appendix A to this Declaration.

### **IV. BACKGROUND**

#### **A. Rheumatic Diseases and their Treatment**

11. Rheumatic diseases, such as rheumatoid arthritis (RA), are characterized by chronic inflammatory symptoms. In adults, RA symptoms include inflammation of the joints, including swelling, pain, and stiffness. RA also involves progressive damage to cartilage and bone, leading to decreased mobility.

Other diseases include psoriatic arthritis, which also causes joint inflammation and damage, but is seen in association with psoriasis. These diseases, and other inflammatory diseases like them, can be severely debilitating, causing not only intense pain but also gradually progressing damage leading to handicap.

12. In children, rheumatic diseases include juvenile idiopathic arthritis (JIA) and its seven subtypes. Certain of these subtypes are treated in essentially the same way as counterpart disease in adults. Children with polyarticular JIA, for example, can be rheumatoid-factor positive, and their disease is essentially identical to adult RA. Children with juvenile psoriatic arthritis may also present very similar symptoms and disease progression as adult psoriatic arthritis.

13. In adults and children with these rheumatic diseases, drugs are used to treat the symptoms of the disease. Additionally, one category of drugs known as disease modifying anti rheumatic drugs (DMARDs) more aggressively treat the diseases and can slow the damage caused by the arthritis. Except in patients which present with more severe or advanced disease, methotrexate is often the first DMARD prescribed for, for example, RA and rheumatoid-factor positive JIA. As the disease progresses, more potent drugs, such as the so-called anti-TNF $\alpha$  drugs, are usually prescribed.

14. The first anti-TNF $\alpha$  drugs approved in the U.S. were Remicade® and Enbrel®, both biologic products approved in 1998 which target and bind to TNF $\alpha$ .

Remicade® is a recombinant antibody intended for I.V. infusion, while Enbrel® is a soluble receptor for TNF $\alpha$  bound to a portion of an antibody intended for weekly subcutaneous injection. Both have often been used as the next DMARD prescribed if methotrexate is not sufficiently effective or an untoward reaction to it occurs.

**B. Humira®**

15. Humira® is a biologic pharmaceutical containing the active agent adalimumab, which is “a recombinant human IgG1 monoclonal antibody specific for human tumor necrosis factor (TNF).” Ex. 1205, 1. Humira® has been approved by the FDA for treatment of moderate to severe rheumatoid arthritis since late 2002, and adalimumab (also known as D2E7) has been recognized as a protein with promising activity in rheumatoid arthritis for nearly two decades. *See id.*; Ex. 1273, 4.

16. By November 2007, Humira® had been widely studied in and used in the treatment of rheumatoid arthritis and for several other inflammatory conditions. For example, Humira® was approved for treatment in psoriatic arthritis in 2005. *See* Ex. 1274. Several additional conditions had either become approved indications in the use of Humira® or would have been under active regulatory review during this time period. These additional conditions included ankylosing spondylitis, Crohn’s Disease, plaque psoriasis, and juvenile idiopathic arthritis. *See* Ex. 1275; Ex. 1206; Ex. 1276; Ex. 1277.

17. Humira® was originally approved for use in a 40 mg per 0.8 mL dose, which equates to a 50 mg/mL concentration. Ex. 1205, 1. According to the Humira® label:

Each 0.8 mL HUMIRA contains 40 mg adalimumab, 4.93 mg sodium chloride, 0.69 mg monobasic sodium phosphate dihydrate, 1.22 mg dibasic sodium phosphate dihydrate, 0.24 mg sodium citrate, 1.04 mg citric acid monohydrate, 9.6 mg mannitol, 0.8 mg polysorbate 80 and Water for Injection, USP.

This was the only formulation available on the market through 2007. *See* Ex. 1206. In fact, this formulation was the only formulation available through most of 2015, when a higher concentration formulation was approved. *See* Ex. 1251. This higher concentration formulation was a 40 mg per 0.4 mL dose, equating to 100 mg/mL, and it contained only mannitol, polysorbate 80, and water. *Id.* at 24. One clear difference in the formulations is that phosphate and citrate, which acted as buffers in the first formulation and accounted for more than half of the listed excipients, were absent in the later formulation.

18. I have prescribed Humira® for pediatric patients with several types of rheumatic disease within months of it coming on the market in 2003, although such usage would have been considered “off-label” as the first pediatric indication was not until 2008. *See* Ex. 1275, 1. “Off-label” prescription of drugs are legal and very common. This is especially true in the world of pediatric care where, due to the few drugs approved for use in children, physicians often must rely on off-label



prescriptions. It has been estimated that “80 percent of drugs prescribed for children are administered for unindicated uses.” Ex. 1278, 139.

19. My use of Humira® was generally in children from around 5 years of age through college students at 21 years old. As Humira® had initially only been tested in and approved for the treatment of adults, my prescription of Humira® had to take into account that children can be much smaller than adults. As such, for my older (and larger) patients, I prescribed the indicated course of treatment of one full injection every other week, while for smaller patients, I asked parents to inject only half of the product and to dispose of the remainder. This decision was guided by my years of experience as a doctor and by my knowledge of how other anti-TNF drugs were used in children. By the time Humira® was on the market, another anti-TNF drug, Enbrel®, contained instructions for weight-guided dosing in children. Ex. 1279, 24. Finally, as a member of the community of pediatric rheumatologists, I was aware of the size-based doses administered in the studies which eventually led to Humira®’s being approved for the treatment of juvenile idiopathic arthritis. *See* Ex. 1275. As such, my prescription of Humira® to children closely aligned with the dosing instructions that eventually accompanied the approved indication for juvenile idiopathic arthritis. *Id.* at 1.

20. In my experience, many rheumatologists with pediatric patients were prescribing Humira® to those patients during this period. In prescribing Humira®

to pediatric patients, I have interacted with the patients and their parents, and I have received feedback on the patient's experience in the use of the drug from them.

## **V. PATIENT EXPERIENCE IN THE USE OF RHEUMATIC DISEASE TREATMENTS**

### **A. Humira® Causes Injection Site Pain**

21. When Humira® first became available, it was my experience that many patients, parents, and medical practitioners were interested in a new therapy. Some patients were no longer responsive to existing treatments and some were interested in a treatment with the convenience of subcutaneous dosage (over the intravenous Remicade®). However, practitioners were aware that some patients experienced injection site pain when taking Humira®. These reports are confirmed in literature that was available in November of 2007, which I discuss in more detail in Section VI(A), below. Because of these injection-pain problems, I would counsel patients about the possible pain that they might experience when using Humira® when discussing the potential benefits and detriments of available therapies.

22. Almost immediately following the earliest uses of Humira®, I heard from many of my patients that the injection site pain was a serious issue. Although tolerance to pain can vary widely between patients, in my experience approximately 95% of my patients have reported pain with the injection of

Humira®. For some of these patients, the pain was unpleasant but bearable, and the patients learned to cope with the pain over time. However, for a significant portion of my patients, which I estimate as approximately 10-20%, the every-other-week Humira® injection became a dreaded event and sometimes devolved into a struggle for parents to get the patients to take the injection.

23. As such, the pain issues in Humira® presented a real and definite issue which adversely impacted patient compliance. In my younger patients whose injections were administered by their parents, these injections could become a major source of conflict. The anticipation of the pain from the scheduled injection sometimes had serious impacts on mood where patients' dread at the upcoming injection could almost be overwhelming. In some of these patients, this extreme unwillingness amounted to refusal to take their injection and necessitated counseling, longer periods between injections, or changes in treatment to another therapy. In some of my older patients whose injections were self-administered, issues of pain could result in failure to comply with dosing instructions. Patient compliance is an important issue, and the failure of a patient to take a drug can pose a problem regardless of how effective a drug may be. The painful injections associated with Humira® led to skipped injections and to the interval between injections stretching from two weeks to much longer periods with potentially serious impacts on the efficacy of the treatment.

24. Although my personal experience of pain reported in the use of Humira® is limited to my pediatric practice which consists largely of children and a small number of early-college-aged adults, the experience of these patients is experienced across all patient populations. Although adults may have increased tolerance to pain compared to children, an increase in the tolerance of pain does not mean a decrease in pain experienced. As such, while the rate of reported pain and of patients unable to deal with the pain of Humira® injections would naturally be less in adults than in children, pain would still likely be experienced across both child and adult patient populations.

**B. The Pain of Humira® Injection Is Not Due to Injection Alone and Is Not Found in Other Rheumatic Disease Treatments**

25. When I prescribed Humira® from the time of its availability to the priority date of the '619 patent, the majority of my patients had already received treatment for their conditions, usually other injectable therapies. A standard progression of treatment usually began, when possible, with the use of milder therapies, such as local injections into affected joints or injections of methotrexate. For patients with more advanced disease or certain diagnoses, the anti-TNF treatments Enbrel® or Remicade® were then used, with a preference for Enbrel® as a subcutaneous injection which could be administered at home instead of requiring hours-long intravenous infusion at a doctor's office as Remicade® does. *See* Ex. 1280; Ex. 1281. Because these drugs had been on the market longer, they

were often the first anti-TNF agent used. I personally had more experience with them and thus greater comfort with their use. In addition, Enbrel® included pediatric use data from its approval date. Ex. 1280, 4. As such, almost every Humira® patient in my practice had been treated with other injectable therapies prior to their use of Humira®.

26. In my experience, patients who had been treated with Humira® and other injectable treatments such as methotrexate or Enbrel®, the use of Humira® was accompanied by more pain in the vast majority of patients. For my patients, pain issues with methotrexate or Enbrel® were largely attributed to the injection itself (i.e., the needle stick), while the drugs themselves were rarely described as being particularly painful. Pain was such a minor issue for some of these patients that methotrexate specifically was capable of being administered by parents while the patient slept. Similar administration of Humira®, however, was not feasible due to the painful nature of the injection.

27. Although there are compliance issues with injectables in children, in my experience the degree of patients' delaying or skipping doses is much greater in those on Humira® compared to methotrexate or Enbrel®. The number of patients who actually discontinue the drug due to the injection experience is almost, but not quite, exclusively in those receiving Humira®.

## **VI. OVERVIEW OF THE PRIOR ART**

### **A. Injection Site Pain Was a Known Reaction to Humira®**

28. My experience with my patients' experiencing pain with Humira® injections was not unique. The Humira® Label disclosed that "[t]he most common adverse reaction with HUMIRA was injection site reactions," which includes injection site pain. Ex. 1205, 6. Injection site pain specifically was reported in 12% of patients administering Humira® and 12% administering the placebo for Humira® during placebo-controlled studies referred to in the Label as "Studies I, II, III, and IV." *Id.* at 7-8. In my opinion, this number is not the proportion of patients who experienced pain, but rather the percentage of patients who experienced pain to such a degree that they felt it necessary to report it. The fact that this same high 12% of patients taking placebo injections also reported pain suggests that the pain associated with Humira® is caused by the formulation components, rather than the active adalimumab antibody itself. As I discuss in Section VI(B), below, injection site pain has been linked with the buffer ingredients used in Humira®. These buffers were present in the Humira® formulation itself, but also in the placebo formulations used in the trials.<sup>1</sup> That

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<sup>1</sup> Fischkoff disclosed a placebo-controlled study of adalimumab (D2E7) which describes the placebo used as "citrate-phosphate buffer without D2E7." *See* Ex.1210 ¶¶ 120. A person reading Fischkoff and the Humira® Label would

Humira® was known to be associated with injection pain was admitted in much of its marketing materials, where pain with injection was indicated as an expected side effect of Humira® on its website. *See* Ex. 1271.

29. The fact that the injection pain is attributable to the Humira® formulation is also supported by prior publications. For example, before November 2007, marketing materials for Humira® indicated that the injection of the needle may cause slight pain or stinging but that the medicine itself may cause a burning sensation. *Id.* Additionally, articles summarizing biologic drugs for the treatment of psoriasis discussed drugs which were approved for or being investigated for the treatment of psoriasis and particularly note injection site pain as a reaction to Humira® but not to other drugs. One article discussed a small number of drugs, and of those, three were administered as subcutaneous injections: Raptiva®,

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understand this study to be the same as “Study IV” in the Humira® Label, as both studies are reported to have analyzed 636 patients receiving adalimumab or placebo every other week for 24 weeks, both allowed for patients to continue their current therapies if the therapy was stable for at least 28 days, and both reported 53% ACR20 response to adalimumab at week 24. *Compare* Ex. 1205, 2, 4 with Ex. 1210 ¶¶ 116-117, 149. As such, a person reading Fischkoff and the Humira® Label would understand the placebo used in the studies in the Humira® Label to be “citrate-phosphate buffer without D2E7.”

Enbrel®, and Humira®. Ex. 1282, 8. Of these three, only Humira® was reported to have injection site pain as a common adverse event. *Id.* A similar paper discussing etanercept (Enbrel®), infliximab (Remicade®), and adalimumab (Humira®) reports injection site pain only for Humira®, stating that “injection-site pain was the major side effect with the use of that agent.” Ex. 1243, 8.

30. As such, it is clear that the use of Humira® was associated with injection site pain, and that the excipients in the injected product were likely responsible for increased pain.

**B. Injection Site Pain Has Been Clearly Linked to the Buffers Used in Humira®**

31. According to the Humira® label:

Each 0.8 mL HUMIRA contains 40 mg adalimumab, 4.93 mg sodium chloride, 0.69 mg monobasic sodium phosphate dihydrate, 1.22 mg dibasic sodium phosphate dihydrate, 0.24 mg sodium citrate, 1.04 mg citric acid monohydrate, 9.6 mg mannitol, 0.8 mg polysorbate 80 and Water for Injection, USP.

Ex. 1205, 1. As such, the 40 mg/0.8 mL formulation of Humira®, the only formulation which was available as of November 2007, contained a citrate-phosphate buffer system.

32. Certain buffers have been linked with pain on injection. For example, prior to November 2007, it was known that citrate and high concentrations of



acetate were painful when injected. Ex. 1241, 2:4-3:2. Indeed, this had long been known for citrate buffers specifically, which had been repeatedly linked with increased pain on injection in reports going back to at least the early 1990s. Ex. 1217, 297 (“[C]itrate is known to cause stinging upon injection.”); Ex. 1221, 218 (comparing commercially-available human growth hormone formulations and concluding that the citrate-buffered product caused significantly more pain on injection than the histidine-buffered product); Ex. 1222 (demonstrating that formulations containing citrate and citrate solutions cause significantly more pain on injection than albumin solutions and saline solutions). One of these studies, in particular, showed that a subcutaneous drug’s citrate buffer caused enough pain on injection that it occasionally precluded self-administration of the drug. *See* Ex. 1222, 553 (“[L]ocal pain at the injection site is a common adverse event, sometimes precluding self-administration. . . .” and “. . . the local pain experienced after subcutaneous administration of epoetin alfa preparations is mainly caused by the citrate component of the buffered solution.”).

33. In fact, as a result of these injection pain issues, many companies attempted to develop products without using a citrate buffer. For example, U.S. Patent No. 6,696,056 discloses a motivation to develop a drug formulation without citrate, because the commercially-available formulation contained citrate and was associated with pain. Ex. 1283, 2:35-38 (“These formulations are clinically

documented to commonly cause patient discomfort associated with s.c.

administration of the citrate-buffered formulations.”). Further, Kaisheva disclosed that injection pain was a factor influencing the selection of a buffer component. Ex. 1220 ¶50 (“Citrate and phosphate buffers are much less preferred because [they cause] a painful reaction when injected subcutaneously.”).

34. While citrate specifically appears to be clearly associated with increased injection site pain, high buffer capacity generally has also been linked to such pain. One study tested the pain experienced in volunteers who received injections of several formulations with different concentrations of phosphate buffer. Ex. 1219, 1013. Noting that phosphate was chosen “because citrate buffer causes pain,” the study concluded that injection site pain corresponded with higher concentrations of buffer. *Id.* at 1012. As such, the study concluded that lower buffer strength generally was desirable to minimize pain in injection. *Id.* at Abstract (“[F]or subcutaneous injections at non-physiological pH, the buffer strength should be kept as low as possible to avoid pain upon injection.... [A] lower buffer strength enables more rapid normalization of the pH at the injection site.”). As discussed above in paragraph 32, high concentrations of acetate were also associated with pain, indicating that the concept of pain on injection with high buffer capacity formulations may be generalizable beyond phosphate. Thus, not only would a drug developer have been motivated to minimize the amount of

buffer present in a formulation, but such a developer would have been motivated to remove the buffer from the formulation altogether.

35. As such, it is my opinion that buffers, such as citrate, were associated with increased injection site pain. As a result, it would have been preferable to eliminate extraneous buffer from these formulations, or at least to minimize it, to address these injection pain issues.

**C. There Would Have Been a Motivation to Remove or Modify the Buffers in Humira®**

36. As discussed in Section V(A) above, my experience in prescribing Humira® shows pain to be a real and serious problem with consequences ranging from discomfort to noncompliance to the inability of the drug to be used in certain patients. As discussed in Section VI(A) above, that Humira® was associated with injection pain is clearly documented in the prior art and would have been known to those familiar with Humira® as of November 2007.

37. As discussed in Section V(B) above, it is my experience that the injection site pain of Humira® is not solely due to the injection of the needle, but is attributable to something in Humira® but not in other treatments such as methotrexate and Enbrel®. As discussed in paragraphs 28-30 above, the art available as of November 2007 also supports that the pain experienced upon injection of Humira® is not merely attributable to pain of the needle's penetrating the skin. It is more highly reported than other injectable treatments. As such, those

familiar with Humira® as of November 2007 would have suspected that something about the formulation of Humira® itself was responsible for the increased pain in Humira®.

38. As discussed in Section VI(B) above, it was known in the art that citrate and other buffers were associated with increased pain. As Humira® was known to contain citrate buffer, those familiar with Humira® as of November 2007 would have been motivated to create a different formulation without citrate (or any extraneous buffer), just as described in the '619 patent.

39. Further, AbbVie themselves were apparently motivated by pain associated with Humira® to remove the citrate buffer from the formulation. In applying to the FDA for approval of a new formulation of Humira®, AbbVie's rationale was in part that "the new formulation may contribute to increased patient comfort through less injection-related pain based on reduced injection volume *and removal of some of the excipients in the currently marketed formulation that may contribute to pain sensation.*" Ex. 1284, 3. Specifically, Abbvie explains that the formulation does not contain sodium chloride, sodium citrate, disodium phosphate dehydrate, and sodium dihydrogen phosphate dehydrate, leaving only mannitol and polysorbate 80 as excipients from the original formulation. *Id.* at 5. Of the components that had been eliminated, it would have been recognized that sodium

chloride was unlikely to contribute to injection pain, inasmuch as many injectable drugs had been formulated in saline solution.

40. Similarly, a published study involving this new formulation designed and funded by AbbVie discussed that the new formulation “was developed to address pain associated with injection,” where injection site reactions including pain were acknowledged as the most common adverse event reported in Humira®. Ex. 1285, 258. The publication specifically explained that such pain “can be influenced by various factors, including the inactive ingredients of the formulation (e.g., citrate buffer)....” *Id.* Finally, the publication explained that the new formulation had fewer ingredients, and that “particularly, there is no citrate buffer.” *Id.*

41. It is my opinion that as of November 2007, there would have been motivation to remove or replace the buffer system used in Humira®.

## **VII. CROSS EXAMINATION AND OATH**

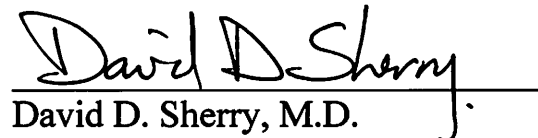
42. I recognize that this declaration will be filed as evidence in a contested case before the Patent Trial and Appeal Board of the United States Patent and Trademark Office. I also recognize that I may be subject to cross examination in the case and that cross examination will take place within the United States. If cross examination is required of me, I will appear for cross examination within the United States during the allotted time for cross examination.

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43. All statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that will false statements and the like so made are punishable by fine or imprisonment or both under 18 USC § 1001.

Dated: 30 Jan 2017

  
David D. Sherry, M.D.

## APPENDIX A - LIST OF EXHIBITS CONSIDERED

Exhibit No.	Document
1201	U.S. Patent No. 9,085,619, Fraunhofer et al.
1205	HUMIRA® Label (Jan. 2003)
1206	HUMIRA® Label (Jan. 2008)
1210	U.S. Pub. No. 2003/0206898, Fischkoff et al.
1217	Gokarn et al., “Excipients for Protein Drugs,” Ch. 17 in Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems (Ashok Katdare & Mahesh V. Chaubal eds., 2006)
1219	Fransson & Espander-Jansson, “Local Tolerance of Subcutaneous Injections,” J. Pharm. Pharmacol., 48:1012-1015 (1996)
1220	U.S. Pub. No. 2003/0138417, Kaisheva et al.
1221	Laursen et al., “Pain Perception after Subcutaneous Injections of Media Containing Different Buffers,” Basic & Clinical Pharmacology & Toxicology, 98:218–221 (2006)
1222	Frenken et al., “Identification of the Component Part in an Epoetin Alfa Preparation that Causes Pain after Subcutaneous Injection,” American J. of Kidney Diseases, 22(4): 553–556 (1993)
1241	WO 2006/138181, Gokarn et al. (filed as PCT/US2006/022599)
1243	Gottlieb, “Efficacy and Safety of Anti-TNF- $\alpha$ Agents in Psoriasis,” in Anti-TNF- $\alpha$ Therapies in the Treatment of Dermatologic Diseases at 6 (2005) (Supplement to Skin & Allergy News; Produced in Affiliation with the Skin Disease Education Foundation’s 29 <sup>th</sup> Annual Hawaii Dermatology Seminar)
1251	HUMIRA® Label (Nov. 2015)
1271	“Injection Tips,” Humira.com, <a href="http://www.humira.com/hu/hustore/cgi-bin/ProdSubEV_Cat_205043_SubCat_210170_NavRoot_205042_NavID_301.htm">http://www.humira.com/hu/hustore/cgi-bin/ProdSubEV_Cat_205043_SubCat_210170_NavRoot_205042_NavID_301.htm</a> [ <a href="http://web.archive.org/web/20050317083331/http://www.humira.com/hu/hustore/cgi-bin/ProdSubEV_Cat_205043_SubCat_210170_NavRoot_205042_NavID_301.htm">http://web.archive.org/web/20050317083331/http://www.humira.com/hu/hustore/cgi-bin/ProdSubEV_Cat_205043_SubCat_210170_NavRoot_205042_NavID_301.htm</a> ] (Archived Mar. 17, 2005)
1273	van de Putte, et al., A Single Dose Placebo Controlled Phase I Study of the Fully Human Anti-TNF Antibody D2E7 in Patients with Rheumatoid Arthritis, Arthritis Rheum., 41(9), S57 (September 1998).

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1274	HUMIRA® Label (Oct. 2005)
1275	HUMIRA® Label (Feb. 2008)
1276	HUMIRA® Label (Feb. 2007)
1277	HUMIRA® Label (Nov. 2006)
1278	Meadows & Hollowell, “‘Off-label’ drug use: an FDA Regulatory Term, Not a Negative Implication of Its Medical Use,” Int’l J. Impotence Research 20:135-144 (2008)
1279	ENBREL® Label (Sept. 2002)
1280	ENBREL® Label (Nov. 1998)
1281	REMICADE® Label (Aug. 1998)
1282	Tsourounis, Biologic Therapies for the Treatment of Chronic Plaque Psoriasis, Formulary 40:184-199 (June 2005)
1283	U.S. Patent No. 6,696,056, Cheung et al.
1284	“Summary Review for Regulatory Action,” by Sarah Yim, Division of Pulmonary, Allergy, and Rheumatology Products (U.S. Food & Drug Administration), of Humira® (2015)
1285	Nash, Randomized Crossover Comparison of Injection Site Pain with 40 mg/0.4 or 0.8 mL Formulations of Adalimumab in Patients with Rheumatoid Arthritis, Rheumatol Ther 3:257-270 (2016)



# EXHIBIT A

THE CHILDREN'S HOSPITAL OF PHILADELPHIA &  
THE UNIVERSITY OF PENNSYLVANIA

Curriculum Vitae

Date: July 2016

David Dan Sherry, M.D.

Office Address: Division of Rheumatology  
10<sup>th</sup> Floor, Colket  
3415 Civic Center Blvd.  
Philadelphia, PA 19104

Personal Married: Coleen Donohoe 1973  
Son: Xander 1977  
Daughters: Grahame 1979  
Rose 1983  
Molly 1986  
Grace 1989

Education:

Pregraduate Training:

1970-74	no degree	Texas Tech University, Lubbock Texas
1974-77	M.D.	Texas Tech University School of Medicine, Lubbock, Texas

Postgraduate Training and Fellowship Appointments:

1977-78	Internship, Pediatrics: Duke University Medical Center, Durham, North Carolina
1978-80	Residency, Pediatrics: Duke University Medical Center, Durham, North Carolina
1980-82	Fellowship, Pediatric Rheumatology: University of British Columbia, British Columbia, Canada

Faculty Appointments:

1982-84	Assistant Clinical Professor of Pediatrics, University of Southern California, Los Angeles, California
1984-91	Assistant Professor of Pediatrics, University of Washington, Seattle, Washington
1991-2002	Associate Professor of Pediatrics, University of Washington, Seattle, Washington
2002-	Professor of Pediatrics, University of Washington,

2002 – present	Seattle, Washington Professor of Pediatrics at The Children's Hospital of Philadelphia, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania
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Hospital and Administrative Appointments:

1982-84	Full-time Staff, Division of Rheumatology and Rehabilitation, Childrens Hospital of Los Angeles, Los Angeles, California
1984-2002	Full-time Staff, Director of Pediatric Rheumatology, Children's Hospital & Regional Medical Center, Seattle, Washington
2002 - present	Full time Staff, Chief Rheumatology Section, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania

Specialty Certification:

1979	National Boards, #191151
1981	Pediatrics, #131939
1992, 1999, 2006	Pediatric Rheumatology, #043160

Licensure:

North Carolina, 1979, 23971 (expired)  
California, 1982, #G47407 (expired)  
Washington, 1984, # 21711 (expired)  
Alaska, 1998, # 3859 (expired)  
Pennsylvania 2002, #MD419759  
DEA, # AS1597181

Awards, Honors and Membership in Honorary Societies:

1977	West Texas Children's Foundation Award
1977	Merck Award
1997	Pediatric Resident's Outstanding Teacher
1998	Thank You Award, Boeing Employees Community Fund
2001	Medical Staff Caring for Children Award
2001, 2002	Top Doctor in Seattle
2002	Family-Centered Care Recognition Award
2001-2014	Top Doctor in America
2004-2014	Top Doctor in Philadelphia
2002-2003	ACR/REF/Amgen Visiting Pediatric Rheumatologist Award
2006	University of Pennsylvania Blockley-Osler Clinical Teaching Award
2007	Arthritis Foundation Quality of Life – Patient and Community Services Award

2008	Master Clinician Award, Children's Hospital of Philadelphia
2009	American Academia of Pediatrics James T. Cassidy Award
2014	ACR/REF/Amgen Visiting Pediatric Rheumatologist Award
2014	ACR Distinguished Fellowship Program Director Award

#### Membership in Professional and Scientific Societies:

##### National Societies:

American College of Rheumatology (Fellow)

##### National Committees:

Executive Committee, Rheumatology Section, American Academy of Pediatrics, 1988 – 1991

Executive Committee, Pediatrics Section, American College of Rheumatology, 1996 – 2000

American Board of Pediatrics, Rheumatology Sub-board member, 2000 – 2005, Chairman, 2003-2005

American Board of Pediatrics, Rheumatology Sub-board medical editor, 2006- present

Co-chairman, Abstract selection committee, American College of Rheumatology 1999-2000

Chairman, Abstract selection committee, American College of Rheumatology 2000-2001

Member, Planning and Meeting Committee, American College of Rheumatology 2000-2003

Member, American Pain Society, Guidelines Committee for Arthritis Pain 2000-2002

Executive Committee Member, Spondyloarthropathy Association of American, 2000 – 2003

##### Local Committees:

Councilor, Northwest Rheumatism Society 1988-1990

Faculty Advisor for Resident Clinical Pathologic Conferences 1993-1996

Faculty Senator for Department of Pediatrics, 1996 - 1998

Member, Institutional Review Board 1998-2000

#### Editorial Positions:

Pediatric Rheumatology for emedicine.com

Journal of Pediatric Rehabilitation Medicine

Pediatric Clinics of North America, Pediatric Rheumatology Edition, April 2012 with Ron Laxer

#### Major Teaching and Clinical Responsibilities:

Primary clinical mentor for Pediatric Rheumatology fellows (Esi DeWitt, MD 2002-2005, Frank Pessler, MD, PhD, 2003-2006, Bitu Arabshahi, MD, 2003-2006, Edward Behrens, MD, 2004-2007, Timothy Beukelman, MD,

2004-2007, Pamela Weiss, MD 2005-2008, Tracey Wright, MD, 2005-2008, Eric Hanson, MD, 2005-2009, Sharon Bout-Tabaku, MD, 2006-2009, Jay Mehta, MD, 2006-2009, Scott Lieberman, MD, PhD, 2007-2010, William Bernal, MD, MPH, 2007-2010, Melissa Lerman, MD, PhD, 2008-2011, Homaira Rahimi, 2008-2011, Scott Canna, MD, 2009-2012, Cara Hoffart, DO, 2009 – 2012, Andrea Knight, MD 2010-2013, Melissa Mizesko, MD, 2010-2012, Lehn Weaver, MD, PhD, 2011- present, Yongdong Zhao, MD, PhD, 2011-2013, Elaine Ramsay, MD 2012-present, Alysha Taxter 2012-present, Karen James, MD 2013-present, Matthew Basiaga, DO 2013-present)

Recent (last 5 years) Continuing Medical Education given (excluding National & International invited lectures):

Group Health Cooperative, Primary Care Sports Medicine, Don't get Burnt: Usual Symptoms, Unusual Diseases  
 Pacific Northwest Dermatological Society, Pediatric Symposium, Whistler, British Columbia, May 1999, Rheumatic Skin Manifestations and Treatment  
 Group Health Spondylitis Support Group, Seattle, May 1999, Spondylitis in Children  
 Pediatrics in the Northwest, Seattle, August 1999, Rheumatology Referrals: When to Hold'em, When to Fold'em  
 2<sup>nd</sup> Annual Emergency Services Conference, Marysville, WA October 1999, Musculoskeletal Pains in Children: What You Don't Want to Miss  
 Olympia Pediatric Journal Club, Olympia, Washington, December 1999  
 Management of Chronic Pain with a Podiatric Emphasis Seminar, Seattle, December, 1999, Pain Amplification in Children  
 Current Concepts in Drug Therapy, University of Washington, Seattle, November 2000 Intraarticular Corticosteroids  
 T.L. Staheli Pediatric Orthopedic Seminar –2001, January, 2001, Not all Bone and Joint Pain is Orthopedic  
 American Juvenile Arthritis Organization, Seton Hall, NJ, March 2004 New Options for Treating Rheumatic Disorders in Children  
 The Children's Hospital of Philadelphia, CPC Grand Rounds, May 2004, FUO  
 Arthritis Foundation, December, 2007, Pain Management  
 Arthritis Foundation Family Day, April 2008, Complementary and Alternative Treatments in Childhood Rheumatic Diseases  
 Pediatric Rheumatology for Orthopedics, September 2009, CHOP

Lectures by Invitation (past 7 years):

March 2006	Visiting Professor, St. Peter's Hospital, New Brunswick, New Jersey
April 2006	Kid's Stuff, American College of Rheumatology State of the Art Fellow's meeting. Chicago
April 2006	Complementary and Alternative Medicine in Pediatric Rheumatic Illness, Arthritis Foundation Family Day,

Philadelphia, Pennsylvania

May 2006	Juvenile Rheumatoid Arthritis, Chronic Illness in Teens, FAB For Teens, About Teens, By Teens, West Orange, New Jersey
May 2006	Linking Pain to Mobility, World Federation of Hemophilia Congress, Vancouver, British Columbia
May 2006	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Rheumatology Grand Rounds, Einstein Medical Center, Philadelphia, Pennsylvania
June 2006	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Pediatric Grand Rounds Mayo Clinic, Rochester, Minnesota
June 2006	Northwestern Pediatric Society Lecture: Amplified Musculoskeletal Pain in Children – When Children Hurt Too Much, Topics and Advances in Pediatrics, University of Minnesota, Minneapolis, Minnesota
July 2006	Musculoskeletal Pain in Children with Marfan syndrome, workshop. National Marfan's Association Meeting, Philadelphia, Pennsylvania
Sept 2006	Amplified Pain: When it Hurts Too Much!, Pediatric Refresher Course, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
Oct 2006	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Pediatric Rheumatology for the Practitioner, New Brunswick, New Jersey
Nov 2006	The Role of the Pediatric Rheumatology Team in Improving the Quality of Life in Children with Arthritis, Association of Rheumatology Health Professionals, Annual Meeting, Washington, DC
Nov 2006	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Pediatric Grand Rounds Einstein Medical Center, Philadelphia, Pennsylvania.
Feb 2007	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Pediatric Anesthesia Rounds, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
April 2007	Pharmacological Issues in Rheumatology, Nurse Practitioners, The Children's Hospital of Philadelphia, Philadelphia, Pennsylvania
April 2007	Therapy and Emerging Therapy for Juvenile Idiopathic Arthritis in Children, Arthritis Foundation Family Day, Philadelphia, Pennsylvania

May 2007	The Philly Way. CRPS workshop, Stanford, Palo Alto, California
June 2007	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Rheumatology Grand Rounds, Hospital for Special Surgery, New York
June 2007	X-Files in Rheumatology. Pediatric Grand Rounds, Mt. Sinai Medical Center, New York
June 2007	Amplified Musculoskeletal Pain In Sports. Sport and Rheuma bei Kindern. Garmisch-Partenkirchen, Germany
June 2007	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Pediatric Grand Rounds, The Medical University of Graz, Graz, Austria.
July 2007	Pain and Pain Management in Juvenile Idiopathic Arthritis, American Juvenile Arthritis Organization, National Meeting, Hershey, PA
October 2007	Pediatric Rheumatology Problems for Rheumatologists, X-files of Pediatric Rheumatology, Amplified Musculoskeletal Pain in Children, Norwegian Pediatric Society, Norway
October 2007	Fibromyalgia and other Amplified Pains, North American Society of Pediatric Gastroenterology, Hepatology and Nutrition, National Meeting, Salt Lake City
November 2007	Difficult Complex Regional Pain Syndrome, American College of Rheumatology, National Meeting, Boston
January 2008	Amplified Musculoskeletal Pain Syndromes in Children, Pain Management and Physical Activity in Pediatrics, Hvidovre Slot, Denmark.
May 2008	X-files from the Rheumatology Clinic, Resident conference, University of Alabama, Birmingham
May 2008	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Pediatric Grand Rounds, University of Alabama, Birmingham
June 2008	Amplified Musculoskeletal Pain in Children – When it Hurts Too Much, Pediatric Grand Rounds, New York University, New York
May 2009	Chronic Pain Syndromes in Children. 10 <sup>th</sup> Annual Advance Practice Nurse Conference, Philadelphia
May 2009	Amplified Musculoskeletal Pain in Children, Henoch-Schönlein Purpura, Systemic Lupus Erythematosus & Juvenile Idiopathic Arthritis, American Academy of Pediatrics, Practical Pediatrics CME Course, Seattle

September 2010	Amplified Pain in Children. Anesthesiology Grand Rounds, Hershey, Pennsylvania
June 2011	Pediatric Rheumatology Objective Structured Clinical Evaluation. Pediatric Rheumatology Symposium, Miami
October 2011	Problems Pediatric Rheumatology. Bone Health Conference, Children's Hospital of Philadelphia
January 2012	Amplified Pain in Children. Anesthesia didactics, Children's Hospital of Philadelphia
February 2012	Henoch Schönlein Purpura. Rheumatology Grand Rounds, Children's Hospital of Philadelphia
March 2012	Idiopathic Pain Amplification Syndrome in Children, NYU 3 <sup>rd</sup> Annual Pediatric Rheumatology Update for Clinicians, New York City
January 2013	Amplified Pain in Children, Grand Rounds, Montefiore, New York
April 2013	Amplified Pain Syndromes, When it Hurts too Much. Columbia University, Grand Rounds, New York
April 2013	Amplified Pain, When it is and When it Isn't. American College of Rheumatology, State of the Art Meeting, Chicago
April 2013	Pediatric Rheumatology for Adult Rheumatologists. American College of Rheumatology, State of the Art Meeting, Chicago
May 2013	CSL Behring Visiting Professor, AI DuPont Children's Hospital, Wilmington, DE
September 2013	Amplified Musculoskeletal Pain Syndromes. James T Cassidy Lectureship, Columbia Mo
October 2013	Amplified Musculoskeletal Pain. Grand Rounds and visiting professor, SickKids, Toronto, On
August 2014	Amplified Pain. Colombia Rheumatology Annual Meeting
August 2014	Amplified Pain in Children. Grand Rounds, Texas Children's Hospital, Houston, Texas
September 2014	Lupus, Peking Union College Medical Hospital, Beijing, China
September 2014	Amplified Pain in Children. Chinese Pediatric Society Annual Meeting, Chongqing, China
October 2014	Complex regional pain syndrome, American College of Rheumatology, Annual Meeting, Boston



## Bibliography:

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2. Sherry DD, Rothstein R, Petty RE. Joint contractures preceding insulin dependent diabetes mellitus. *Arthritis Rheum* 1982;25: 1362-1364
3. Sherry DD, Kredich DW. Transient thrombocytopenia in systemic onset juvenile rheumatoid arthritis. *Pediatrics* 1985;76:600-603
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5. Petty RE, Sherry DD, Johannson J. Anti-IgA antibodies in pregnancy. *N Engl J Med* 1985;313:1620-1625
6. Petty RE, Sherry DD, Johannson J. IgA anti-IgA2 antibodies: Their measurement by an enzyme-linked immunosorbent assay and their relationship to disease. *Int Arch Allergy Appl Immun* 1986;80:337-341
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*Neurol* 1993;8:256-259

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