United States District Court for the District of Columbia

Novartis Pharmaceuticals Corporation,

One Health Plaza East
Hanover, NJ 07936

Plaintiff,

v.

The Janssen Pharmaceuticals Company of Johnson & Johnson,

One Johnson & Johnson Plaza
News Brunswick, NJ 08933

Defendant.

Case: 1:19-cv-00576 (D Deck)
Assigned To : Bates, John D.
Assign. Date : 3/1/2019
Description: TRO/PI Jury Demand

JURY TRIAL DEMANDED

COMPLAINT FOR INJUNCTIVE AND OTHER RELIEF

Plaintiff Novartis Pharmaceuticals Corporation ("Novartis"), by and through its attorneys, files this Complaint against The Janssen Pharmaceuticals Companies of Johnson & Johnson ("Janssen"). In support of its causes of action, Novartis states as follows:

NATURE OF THE ACTION

1. Novartis seeks to enjoin Janssen's false and misleading advertising claims first launched in January 2019, and to obtain monetary and other relief for damages incurred, under the false advertising of the Lanham Act, 15 U.S.C. §§ 1125(a).

2. Novartis and Janssen manufacture competing drugs, Cosentyx® and Tremfya®, respectively, to treat moderate to severe plaque psoriasis.

3. Janssen presented data from the ECLIPSE study in a false and misleading manner in at least two presentations at conferences within the past two months and is continuing to do so ***right now***. In these presentations, Janssen made claims that its Tremfya® product was both superior and noninferior

to Novartis's Cosentyx® product, but did not present key safety information. Rather, it chose to cherry-pick among the adverse events that were recorded in the study.

4. Psoriasis is a chronic, autoimmune inflammatory disorder that results in the overproduction of skin cells, characterized by raised, inflamed, red lesions, or plaques, which can cause physical pain and itching.[1]

5. Novartis and Janssen manufacture competing drugs, Cosentyx® and Tremfya®, respectively, to treat moderate to severe plaque psoriasis.

6. On December 12, 2018, Janssen announced its results from a study it conducted to compare the efficacy of these products. Termed the ECLIPSE study, it was designed to compare the efficacy of Tremfya® versus Cosentyx® after 48 weeks of treatment in adults with moderate to severe plaque psoriasis.

7. As part of this study, investigators collect safety information. This information is published as part of the study results.

8. The difference in how the adverse events from the ECLIPSE study were portrayed in marketing material versus the poster that presented the scientific results is striking, as shown below:

Figure 1: Janssen's marketing material on ECLIPSE safety findings

[1] American Academy of Dermatology, *What is Psoriasis?* (Nov. 19, 2018) https://www.aad.org/public/diseases/scaly-skin/psoriasis/what-is-psoriasis.

IN MODERATE TO SEVERE PLAQUE PSORIASIS

SAFETY PROFILE FROM THE ECLIPSE STUDY

ECLIPSE: SUMMARY OF SAFETY FINDINGS THROUGH WEEK 56[4]

	TREMFYA® (guselkumab)	COSENTYX® (secukinumab)
ADVERSE EVENT RATES THROUGH WEEK 56		
SAFETY ANALYSIS SET, n	534	511
AVERAGE DURATION OF FOLLOW-UP (WEEKS)	54.90	53.67
≥1 ADVERSE EVENT, n (%)	416 (77.9%)	417 (81.6%)
≥1 SERIOUS ADVERSE EVENT, n (%)	33 (6.2%)	37 (7.2%)
SELECTED ADVERSE EVENTS*		
INFECTIONS, n (%)	313 (58.6%)	331 (64.8%)
SERIOUS INFECTIONS, n (%)	6 (1.1%)	5 (1.0%)
TUBERCULOSIS	0	0
INFLAMMATORY BOWEL DISEASE, n (%)[†]	0	3 (0.6%)
SERIOUS HYPERSENSITIVITY REACTIONS, n (%)[‡]	0	1 (0.2%)[§]

No safety comparisons can be made between TREMFYA® and Cosentyx® based upon this presentation.

*Selected adverse events represent events included in Warnings and Precautions section of the current full Prescribing Information for each product.

†Inflammatory bowel disease includes Crohn's disease, colitis, or inflammatory bowel disease. Of these 3 treatment-emergent adverse events, there was 1 serious adverse event of Crohn's disease.

‡Anaphylactic reactions include adverse events of anaphylactic reaction, anaphylactic shock, anaphylactoid reaction, anaphylactoid shock, and Type 1 hypersensitivity. Serum sickness-like reactions include adverse events of serum sickness and serum sickness-like reaction.

§Anaphylactoid reaction to wasp bite.

SELECTED IMPORTANT SAFETY INFORMATION

TREMFYA® may increase the risk of infection. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a clinically important or serious infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis before treating with TREMFYA®. Avoid use of live vaccines in patients treated with TREMFYA®.

Please see related and other Important Safety Information on back cover.

Tremfya® (guselkumab)

Figure 2: Janssen poster presentation showing the ECLIPSE safety data

Table 3. Key Safety Events Through Week 56

	Guselkumab	Secukinumab
Treated patients, N	534	511
Average duration of follow up (weeks)	54.90	53.67
Average exposure (number of administrations)*	14.65	14.41
Average number of active injections received	6.8	28.8
Patients who discontinued study agent due to ≥1 AE, n (%)	10 (1.9%)	12 (2.3%)
≥1 AE, n (%)	416 (77.9%)	417 (81.6%)
≥1 SAE, n (%)	33 (6.2%)	37 (7.2%)
Overall infections, n (%)	313 (58.6%)	331 (64.8%)
Infections requiring treatment	118 (22.1%)	147 (28.8%)
Serious infections	6 (1.1%)	5 (1.0%)
Malignancy, n (%)	7 (1.3%)	4 (0.8%)
NMSC	6 (1.1%)	2 (0.4%)
Other malignancy	1 (0.2%)	2 (0.4%)
MACE, n (%)**	0	1 (0.2%)
Inflammatory bowel disease, n (%)†	0	3 (0.6%)
ISR to active study agent, n (%)	13 (2.4%)	20 (3.9%)

AE, Adverse event; SAE, Serious adverse event; MACE, Major adverse cardiac event; NMSC, Non-melanoma skin cancer; ISR, Injection site reaction.
*All patients received guselkumab 100 mg at Weeks 0, 4, and every 8 weeks thereafter. All patients received secukinumab 300 mg at Weeks 0, 1, 2, 3, 4, and every 4 weeks thereafter.
**MACE included cardiovascular death, myocardial infarction, and stroke.
†Crohn's disease and ulcerative colitis.

9. Janssen omitted among the most egregious adverse events. This includes malignancies and Major Adverse Cardiac Events ("MACE"). This omission is especially egregious because these adverse events are not in the prescribing information for Tremfya®. In other words, these adverse events would be ***new*** information to dermatologists.

10. This is precisely why the FDA has issued guidance on what companies can say about adverse events. "Drugs and devices are misbranded under the Act if their labeling is false or misleading in any particular (21 U.S.C. 352(a)). Similarly, prescription drugs and restricted devices are misbranded if their advertising is false or misleading in any particular (21 U.S.C. 352(n) & (q)(1); 21 CFR 202.1(e)(5)(i))." *See* FDA's Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion.[2]

[2] U.S. Dept. of Health and Human Serv. Food and Drug Administration, *Guidance for Industry Presenting Risk Information in Prescription Drug and Medical Device Promotion*, hereinafter referred to as "FDA Guidance", 3, https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf

11. Ignoring these prohibitions, Janssen's illegal false advertising is causing, and will continue to cause, massive and irreparable harm to Novartis.

12. Novartis has sent Janssen three separate cease and desist letters in hopes of amicably – and without court intervention – solving this and associated problems in its use of ECLIPSE study data, to no avail.

13. ***Right now***, Janssen is continuing this misleading advertising campaign at the world's largest dermatology event: the Annual Meeting of the American Academy of Dermatology at the Walter E. Washington Convention Center here in the District of Columbia. Over 19,000 attendees and industry professionals, including 10,000 dermatologists, will be potentially exposed to Janssen's false advertising campaign.

14. Novartis therefore respectfully seeks an immediate halt to Janssen's continued false and misleading advertising claims. Janssen's false advertising campaign where they selectively omit key safety information from their marketing materials should be enjoined.

JURISDICTION AND VENUE

15. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 1338 because it arises under the Lanham Act, 15 U.S.C. § 1051 *et seq.* This Court has supplemental jurisdiction over Novartis's state-law claim pursuant to 28 U.S.C. §1367(a) because they are related to Novartis's Lanham Act claim and they form part of the case or controversy.

16. This Court has personal jurisdiction over Janssen pursuant to D.C. Code § 13-423(A)(1),(3), and (4) and the Due Process Clause of the United States Constitution. Janssen transacts business in this district, including without limitation, by selling and marketing its products to residents of the District of Columbia, and by disseminating its misleading advertising that reached viewers in District of Columbia. Janssen also has committed tortious acts within this district by making advertisements and other material misrepresentations of fact to residents of the District of the Columbia.

17. Venue is proper in this Court under 28 U.S.C. § 1391 because a substantial part of the events giving rise to Novartis's claim occurred in District of Columbia.

THE PARTIES

18. Plaintiff Novartis Pharmaceuticals Corporation a pharmaceutical company headquartered at One Health Plaza East Hanover, NJ 07936.

19. Defendant Janssen Pharmaceutical is a pharmaceutical company headquartered in Titusville, New Jersey.

FIRST CAUSE OF ACTION FOR FALSE ADVERTISING

(Lanham Act Violation, 15 U.S.C. § 1125(a))

20. Novartis repeats and realleges each and every allegation contained in paragraphs 1 through 16 as if fully set forth herein.

21. Janssen sells Tremfya® in interstate commerce and is engaging in an advertising Campaign in connection with the marketing of this product.

22. The crux of Janssen's Campaign is that the ECLIPSE study proves that Tremfya® is superior to Cosentyx® but fails to present critical safety information.

23. Janssen's claims made in several industry presentations are false and misleading.

24. These claims represent commercial speech, in that they were made by a party (Janssen) that is in commercial competition with Novartis for the purpose of influencing health care providers to prescribe its product, Tremfya®, and were disseminated sufficiently to the public to constitute "advertising" or "promotion" within this industry.

25. Upon information and belief, Janssen's claims are likely to deceive or confuse a substantial segment of the target audience prescribers.

26. This deceptive conduct by Janssen is and has been willful and deliberate, and has injured and continues to injure Novartis.

27. Janssen knows or should know that the claims it is making regarding Novartis's drug, Cosentyx®, are false and misleading.

28. Janssen advertising violates Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a).

29. Novartis has been and continues to be damaged by Janssen's false advertising, including through direct diversion of sales from Novartis to Janssen and the lessening of the goodwill that Novartis's drug, Cosentyx®, enjoys among health care providers and other audiences.

30. Novartis has no adequate remedy at law to redress these harms.

SECOND CAUSE OF ACTION

(Unfair or deceptive trade practices, § 28-3904(e),(f))

31. Novartis repeats and realleges each and every allegation contained in paragraphs 1 through 27 as if fully set forth herein.

32. Janssen's advertising claims represent that its drug, Tremfya® is superior to Cosentyx® without presenting the key safety information.

33. Janssen's advertising claims are based on the data from the ECLIPSE study.

34. Janssen's failure to accurately present safety information from the ECLIPSE study misrepresents the safety of its product on new safety information that has not been previously available.

35. Janssen's advertising claims omit a critical, material fact about the data from the ECLIPSE study, and the omission tends to mislead.

36. Janssen advertising violates §28-3904 D.C. Unfair Or Deceptive Trade Practices Act.

PRAYER FOR RELIEF

WHEREFORE, Novartis respectfully requests that the Court enter judgment as follows:

A. An Order adjudging that Janssen has violated and is violating Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a) and (c);

B. An Order preliminarily and permanently enjoining Janssen from disseminating or causing the dissemination of the false and misleading claims alleged herein;

C. An Order preliminarily and permanently enjoining Janssen from disseminating or causing the dissemination of any and all other advertisements, packaging, or other promotional materials making

this and comparable claims, whether expressly or by implication, based on selectively presented safety data regarding Tremfya® and Cosentyx® derived from the ECLIPSE study;

D. An Order permanently enjoining Janssen, including without limitation its employees, investigators, and researchers, from making any of the advertising claims challenged as false or misleading in this Complaint in any speaking engagements;

E. An Order permanently enjoining Janssen from making any of the advertising claims challenged as false or misleading in this Complaint in any commercials, advertisements, or other promotional materials;

F. An Order requiring Janssen to disseminate corrective advertising to correct the false and misleading impressions created among prescribers by the false claims contained in the various presentations;

G. An Order directing an accounting by Janssen of their gains, profits, savings, and advantages realized by reason of its false advertising, awarding Novartis damages to the fullest extent allowed by law, and trebling Novartis's recovery pursuant to Section 35 of the Lanham Act, 15 U.S.C. §1117;

H. An Order granting Novartis its costs and disbursements in this action, including its reasonable attorneys' fees; and

I. An Order granting Novartis such other and further relief as this Court may deem just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Novartis demands trial by jury in this action of all issues so triable.

March 1, 2019

By: _____

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CIVIL COVER SHEET

JS-44 (Rev. 6/17 DC)

I. (a) PLAINTIFFS
Novartis Pharmaceutical Corp
One Health Plaza East
Hanover N.J. 07936

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF _____
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
The Janssen Pharmaceutical Company of Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, N.J. 08933

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Scott Winkelman
1001 Penn. Ave. NW
Washington, D.C. 20004

A
Case: 1:19-cv-00576 (D Deck)
Assigned To : Bates, John D.
Assign. Date : 3/1/2019
Description: TRO/PI Jury Demand

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ☒ 3 Federal Question (U.S. Government Not a Party)
- ○ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) FOR DIVERSITY CASES ONLY!

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	○ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT
(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ A. *Antitrust*
- ☐ 410 Antitrust

○ B. *Personal Injury/ Malpractice*
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ C. *Administrative Agency Review*
- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

☒ D. *Temporary Restraining Order/Preliminary Injunction*

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ E. *General Civil (Other)* OR **○ F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc.
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☒ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ G. *Habeas Corpus/ 2255* ☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	○ H. *Employment Discrimination* ☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	○ I. *FOIA/Privacy Act* ☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	○ J. *Student Loan* ☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ K. *Labor/ERISA (non-employment)* ☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	○ L. *Other Civil Rights (non-employment)* ☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☐ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	○ M. *Contract* ☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	○ N. *Three-Judge Court* ☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

☒ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)

Lanham Act 15 U.S.C. § 1125(a)

VII. REQUESTED IN COMPLAINT — CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 — DEMAND $ — JURY DEMAND: Check YES only if demanded in complaint YES ☒ NO ☐

VIII. RELATED CASE(S) IF ANY (See instruction) YES ☐ NO ☒ If yes, please complete related case form

DATE: 3/1/19 SIGNATURE OF ATTORNEY OF RECORD _____

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.