IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
SHERMAN DIVISION

MURRAY AND POOLE ENTERPRISES, LTD.,	)	
Plaintiff,	)	**Civil Action No. 24-cv-00303**
v.	)	**JURY TRIAL DEMANDED**
THE CIGNA GROUP; CIGNA HEALTH AND LIFE INSURANCE COMPANY; CONNECTICUT GENERAL LIFE INSURANCE COMPANY; AND CIGNA HEALTHCARE OF TEXAS, INC.,	)	
Defendants.	)	

ORIGINAL COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiff, Murray & Poole Enterprises, Ltd. ("M&P") by and through its undersigned counsel, for its Complaint against Defendants The Cigna Group ("Cigna Group"), Cigna Health and Life Insurance Company ("CHLIC"), Connecticut General Life Insurance Company ("CGLIC"), and Cigna Healthcare of Texas, Inc. ("Cigna Texas") (collectively, referred to as "Cigna" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

2. This is a civil action for infringement of United States Patents Nos. 10,206,891; 10,265,281; 11,026,899; 11,026,900; and 11,026,901 (collectively, the "Patents-in-Suit") arising under the Patent Laws of the United States, 35 U.S.C. §§ 271 *et seq*.

THE PARTIES

3. Plaintiff M&P is located at Suites 41/42 Victoria House, 26 Main Street, Gibraltar, United Kingdom.

4. Defendant Cigna Group is organized and existing under the laws of Delaware, with a principal place of business located at 900 Cottage Grove Road, Bloomfield, CT, 06002.

5. Defendant CHLIC is organized and existing under the laws of Connecticut, with a principal place of business located at 900 Cottage Grove Road, Bloomfield, CT, 06002.

6. Defendant CGLIC is organized and existing under the laws of Connecticut, with a principal place of business located at 900 Cottage Grove Road, Bloomfield, CT, 06002.

7. Defendant Cigna Healthcare Texas is organized and existing under the laws of Texas, with a principal place of business located at 1640 Dallas Parkway, Plano, TX, 75093. On information and belief, Cigna Texas may be served through its registered agent, CT Corporation System, 1999 Bryan St., Suite 900, Dallas, TX 75201-3136.

JURISDICTION AND VENUE

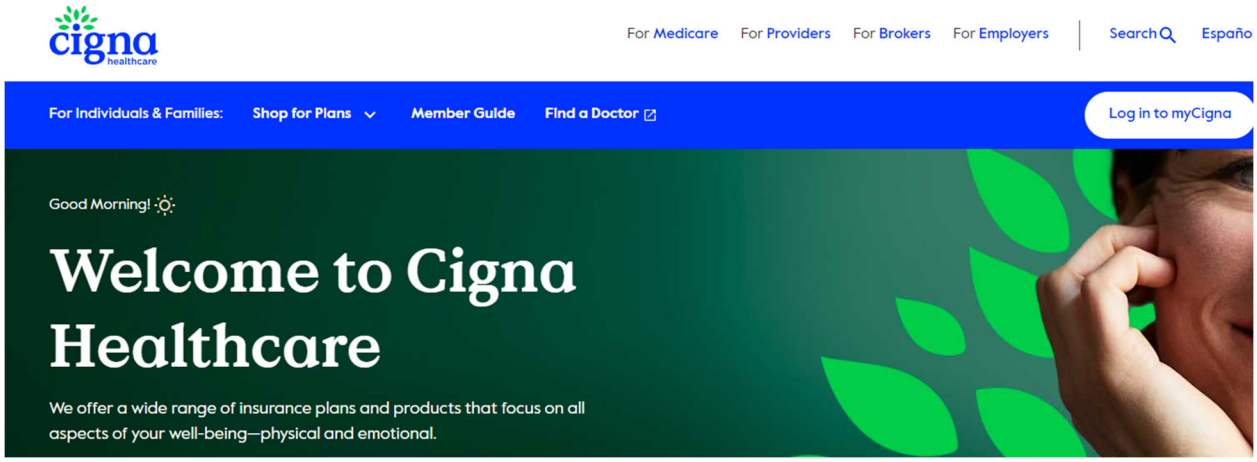
8. Plaintiff incorporates and realleges all of the above paragraphs as though fully set forth herein.

9. This is an action for patent infringement arising under the patent laws of the United States, including 35 U.S.C. §§ 271 *et seq*. The jurisdiction of this Court over the subject matter of this action is proper under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c), and 1400(b).

11. Defendants are part of a multi-national conglomerate that describes itself as a "global health company" that offers health insurance to customers around the world and in the United States, including this District. *See* Cigna FY2023 10-K, p. 1, Exhibit 1. Defendants

regularly conduct business in this District itself, for example, at 1640 Dallas Pkwy., Plano, Texas, 75093, which is the headquarters of Cigna Texas, and Cigna Healthcare, a subsidiary of Cigna Group. *See* Exhibits 2 and 3. On information and belief, Defendants operate as a joint enterprise for conducting business; including the infringing acts below. For example, Cigna Group includes the Cigna Healthcare division, which "provide[s] comprehensive medical plan services and coordinated solutions to clients and customers." *See* Cigna FY2023 10-K, pp. 8-9, Exhibit 1. In addition, on information and belief, Cigna Group owns and operates the Cigna Healthcare website through which individuals are informed about insurance plans and insurance products. *See*, e.g., www.cigna.com.



In addition, Cigna Group defines the term "Cigna Companies" as referring to operating subsidiaries of Cigna Group and states that "[a]ll products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or services company subsidiaries of the Cigna Group."

> "Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.

See Cigna's "Non-Preferred Drug Coverage Review – (Formulary Exception Criteria), p. 132, Exhibit 22.

12. Defendants also operate as a joint enterprise for defending lawsuits. For example, Defendants have previously defended a patent infringement lawsuit together in this District that was brought by a different plaintiff. *See*, *Alexsam v. Cigna*, 2-20-cv-0081 (EDTX, 2020).

13. This Court also has personal jurisdiction over Defendants because Defendants conduct business in this District by at least offering for sale or selling services through its websites, which are accessible in this District, and because infringement has occurred and continues to occur in this District.

14. Defendants have committed and continue to commit acts of infringement in this District.

BACKGROUND OF THE INVENTION

15. Atherosclerosis is a condition that develops when a substance known as "plaque" undesirably builds up inside a person's arteries, thereby restricting or even blocking blood flow in the person's cardiovascular system. Atherosclerosis is widespread within the United States, afflicting about half of Americans between ages 45 and 84. Cardiovascular events associated with atherosclerosis, such as heart attack and ischemic stroke, are the leading cause of death in the United States. Although atherosclerosis is widespread in the U.S. population, the initial stages of atherosclerosis are often undetected. Tragically, people with atherosclerotic vascular disease may experience sudden and severe symptoms, such as a coronary occlusion that results a in heart attack, ischemic stroke and/or sudden death.

16. Colchicine is an anti-inflammatory alkaloid compound that historically has been used to treat gout and gout flare-ups. However, the U.S. Food and Drug Administration (FDA) has

approved a colchicine-containing product known as LODOCO® as a medicament for reducing the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease. *See*, LODOCO® FDA label, Exhibit 4. LODOCO® has been called "the first anti-inflammatory atheroprotective cardiovascular treatment" to be approved by the FDA. See, Description of LODOCO® in Drugs.com webpage, Exhibit 5. A study published in the prestigious New England Journal of Medicine shows that LODOCO® lowers the risk of heart attacks, strokes, stents, and cardiovascular death by 31% in patients with chronic coronary disease. *See*, Nidorf *et al*., N. Engl. J. Med. 2020; 383:1838-1847, at p. 1845, Exhibit 6. In addition, another study published in the New England Journal of Medicine shows that LODOCO® lowers cardiovascular risk after recent myocardial infarction. *See*, Tardif *et al.,* N. Engl. J. Med. 2019; 381:2497-2505, Exhibit 7.

17. LODOCO® is marketed by Agepha Pharma US and is sold in tablet form, with each tablet containing 0.5 mg of colchicine. The recommended dosage for LODOCO® is one 0.5 mg colchicine tablet per day. This dosage allows for long term use by patients to manage their cardiovascular disease associated with atherosclerosis. By contrast, the dosage of colchicine for the treatment of gout is significantly higher (a 0.6 mg colchicine tablet taken up to 2 to 4 times per day). This higher dosage of colchicine can only be tolerated for a short duration, as it carries a risk for renal or hepatic toxicity. *See*, e.g., Karatza *et al.*, Xenobiotica 2021;51:643-656, Exhibit 8 and Robinson P.C. *et al.*, Am. J. Med. 2022; 135:32-38, Exhibit 9. Furthermore, even if a 0.6 mg colchicine tablet is taken once per day, that dosage carries a risk of renal toxicity for patients who have renal impairment. *See* Exhibits 8, 9.

The Patents-in-Suit

18. Plaintiff incorporates and realleges all of the above paragraphs as though fully set forth herein.

U.S. Patent No. 10,206,891

19. U.S. Patent No. 10,206,891 (the "'891 Patent"), entitled "Method of Treating Cardiovascular Events Using Colchicine Concurrently with an Antiplatelet Agent," was duly and legally issued by the United States Patent and Trademark Office on February 19, 2019. The '891 Patent names Mark Nidorf as the sole inventor. A true and correct copy of the '891 Patent is attached hereto as Exhibit 10.

20. M&P is the exclusive owner, by assignment, of all rights, title and interest of the '891 Patent. M&P has the right to bring this suit to recover damages for any current or past infringement of the '891 Patent. *See* Exhibit 11.

21. The '891 Patent is directed to, among other things, a method of treating and/or reducing the risk of a certain cardiovascular events, particularly acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, in a subject. For instance, claim 1 reads as follows:

> 1. A method of treating and/or reducing the risk of a cardiovascular event in a subject, the method comprising:
>
> administering colchicine, a salt thereof, and/or any combination thereof to a subject at risk of a cardiovascular event or who has had a cardiovascular event;
>
> wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke.

U.S. Patent No. 10,265,281

22. U.S. Patent No. 10,265,281 (the "'281 Patent"), entitled "Treatment or Prevention of Cardiovascular Events via the Administration of a Colchicine Derivative," was duly and legally

issued by the United States Patent and Trademark Office on April 23, 2019. The ’281 Patent names Mark Nidorf as the sole inventor. A true and correct copy of the ’281 Patent is attached hereto as Exhibit 12.

23. M&P is the exclusive owner, by assignment, of all rights, title and interest of the ’281 Patent. M&P has the right to bring this suit to recover damages for any current or past infringement of the ’281 Patent. *See*, Exhibit 13.

24. The ’281 Patent is directed to, among other things, a method for treating and/or reducing the risk of a cardiovascular event in a subject by administering a therapeutic amount of a composition that comprises no more than about 0.6 mg of colchicine, a colchicine salt, or a combination thereof. For instance, claim 1 reads as follows:

> 1. A method for treating and/or reducing the risk of a cardiovascular event in a subject in need thereof comprising:
>
> administering to the subject a therapeutically effective amount of a composition comprising no more than about 0.6 total mg of (i) colchicine, (ii) a salt of (i), or any combination of (i)-(ii), wherein the composition is administered once per day,
>
> thereby treating and/or reducing the risk of the cardiovascular event in the subject.

U.S. Patent No. 11,026,899

25. U.S. Patent No. 11,026,899 (the “’899 Patent”), entitled “Treatment or Prevention of Cardiovascular Events via the Administration of a Colchicine Derivative,” was duly and legally issued by the United States Patent and Trademark Office on June 8, 2021. The ’899 Patent names Mark Nidorf as the sole inventor. A true and correct copy of the ’899 Patent is attached hereto as Exhibit 14.

26. M&P is the exclusive owner, by assignment, of all rights, title and interest of the '899 Patent. M&P has the right to bring this suit to recover damages for any current or past infringement of the '899 Patent. *See* Exhibit 15.

27. The '899 Patent is directed to, among other things, a method for treating and/or reducing the risk of a cardiovascular event in a subject by orally administering a composition comprising about 0.5 mg of colchicine, a colchicine salt, or a combination thereof. For instance, claim 1 reads as follows:

> 1. A method for treating and/or reducing the risk of a cardiovascular event in a subject in need thereof, which comprises:
>
> administering to the subject a therapeutically effective amount of a composition comprising about 0.5 total mg of (i) colchicine, (ii) a salt of (i), or any combination of (i) and (ii),
>
> wherein the composition is administered orally and once per day.

U.S. Patent No. 11,026,900

28. U.S. Patent No. 11,026,900 (the "'900 Patent"), entitled "Treatment or Prevention of Cardiovascular Events via the Administration of a Colchicine Derivative," was duly and legally issued by the United States Patent and Trademark Office on June 8, 2021. The '900 Patent names Mark Nidorf as the sole inventor. A true and correct copy of the '900 Patent is attached hereto as Exhibit 16.

29. M&P is the exclusive owner, by assignment, of all rights, title and interest of the '900 Patent. M&P has the right to bring this suit to recover damages for any current or past infringement of the '900 Patent. *See* Exhibit 17.

30. The '900 Patent is directed to, among other things, a method for treating and/or reducing the risk of a cardiovascular event in a subject with clinically stable coronary disease. For instance, claim 1 reads as follows:

> 1. A method for treating and/or reducing the risk of a cardiovascular event in a subject in need thereof, that comprises:
>
> administering to the subject a therapeutically effective amount of a composition comprising about 0.5 total mg of (i) colchicine, (ii) a salt of (i), or any combination of (i) and (ii),
>
> wherein the composition is administered orally and once per day,
>
> and wherein the subject has clinically stable coronary disease.

U.S. Patent No. 11,026,901

31. U.S. Patent No. 11,026,901 (the "'901 Patent"), entitled "Treatment or Prevention of Cardiovascular Events via the Administration of a Colchicine Derivative," was duly and legally issued by the United States Patent and Trademark Office on June 8, 2021. The '901 Patent names Mark Nidorf as the sole inventor. A true and correct copy of the '901 Patent is attached hereto as Exhibit 18.

32. M&P is the exclusive owner, by assignment, of all rights, title and interest of the '901 Patent, and has the right to bring this suit to recover damages for any current or past infringement of the '901 Patent. *See* Exhibit 19.

33. The '901 Patent is directed to, among other things, a method for treating and/or reducing the risk of acute myocardial infarction in a subject by administering an oral composition comprising about 0.5 mg of colchicine, a colchicine salt, or a combination thereof. For instance, claim 1 reads as follows:

> 1. A method for treating and/or reducing the risk of acute myocardial infarction in a subject comprising:
>
> administering to the subject a therapeutically effective amount of a composition comprising about 0.5 total mg of (i) colchicine, (ii) a salt of (i), or any combination of (i) and (ii),
>
> wherein the composition is administered orally and once per day.

Defendants' Infringing Activities

34. Cigna induces patients with atherosclerotic diseases to infringe the Patents-in-Suit. For instance, in Cigna's Formulary Exception Criteria for Non-Covered Products ("Formulary") dated January 1, 2024, Cigna expressly states that for a patient to receive "Locodo" [*sic* LODOCO®], it is a prerequisite that the "[p]atient has tried colchicine 0.6 mg tablets or capsules." *See* Exhibit 20, p. 44. Furthermore, the Formulary includes the phrase "[documentation required]" in bold red letters next to this off-label use requirement, indicating that a patient must document and prove his or her off-label use of 0.6 mg colchicine in order to become eligible to receive LODOCO® for treatment of atherosclerotic disease.

Locodo	colchicine 0.5 mg tablets	Atherosclerotic Disease. Approve if the patient meets ALL of the following (1, 2, 3, and 4): **1.** Patient is ≥ 18 years of age; AND **2.** Lodoco is being added onto a background regimen(s) of other atherosclerotic disease medication(s) **[documentation required]**; AND Note: Examples of medications recommended in guideline-directed therapy for patients with atherosclerotic disease can include aspirin, antiplatelet agents (e.g., clopidogrel, Brilinta [ticagrelor tablets]), anticoagulants, lipid-lowering agents (e.g., statins such as atorvastatin and rosuvastatin), beta blockers, angiotensin-converting enzyme inhibitors, and/or angiotensin receptor blockers. **3.** Patient has a creatinine clearance ≥ 50 mL/min; AND **4.** Patient has tried colchicine 0.6 mg tablets or capsules **[documentation required]**.

35. Upon discovering Cigna's prerequisite for off-label use of 0.6 mg colchicine to treat atherosclerotic disease in Cigna's Formulary, M&P sent a letter to Cigna Group, dated January 4, 2024 ("January 4th Letter"). Exhibit 21. In the January 4th Letter, M&P informed Cigna Group that "LODOCO® is currently the only FDA-approved product for such conditions. There are no other FDA-approved colchicine products for atherosclerotic diseases. Promoting off-label use of a product when there is an FDA-approved product available not only induces infringement of valuable patent rights, but also puts patients at risk due to improper treatment." *See* January 4th Letter, Exhibit 21, at p. 1.

36. In addition, the January 4th Letter noted that "Murray and Poole owns a global patent portfolio including many issued patents as well as pending patent applications relating to its LODOCO®® product. For instance, U.S. Patent Nos. 10,265,281; 9,744,144; 10,206,891; 11,026,899; 11,026,901; and 11,026,900 each relate to treatment of various cardiovascular events by administration of low-dose colchicine." *Id*. The January 4th Letter also suggested that "Cigna should consider carefully Murray and Poole's patent rights in connection with the promotion of any low dose colchicine products that could infringe any Murray and Poole patent rights.." *Id*. at p. 2.

37. Despite being informed of the M&P patent rights on the use of low-dosage colchicine for treating atherosclerotic diseases, a subsequent publication by Cigna still required patients to try 0.6 mg colchicine tablets or capsules before they could become eligible to receive LODOCO®. Specifically, in the document entitled "Non-Preferred Drug Coverage Review – (Formulary Exception Criteria)" ("Formulary Exception Criteria") (Exhibit 22), Cigna merely corrected the earlier misspelling of "LODOCO®" as "Locodo" but maintained all of the other requirements regarding off-label use of 0.6 mg colchicine found in the Formulary, including the requirement to document the patient's off-label use in order to establish eligibility for treatment with LODOCO®. *See*, Formulary Exception Criteria, Exhibit 22, at p. 64.

Lodoco	colchicine 0.5 mg tablets	Atherosclerotic Disease. Approve if the patient meets ALL of the following (1, 2, 3, and 4): **1.** Patient is ≥ 18 years of age; AND **2.** Lodoco is being added onto a background regimen(s) of other atherosclerotic disease medication(s) **[documentation required]**; AND Note: Examples of medications recommended in guideline-directed therapy for patients with atherosclerotic disease can include aspirin, antiplatelet agents (e.g., clopidogrel, Brilinta [ticagrelor tablets]), anticoagulants, lipid-lowering agents (e.g., statins such as atorvastatin and rosuvastatin), beta blockers, angiotensin-converting enzyme inhibitors, and/or angiotensin receptor blockers. **3.** Patient has a creatinine clearance ≥ 50 mL/min; AND **4.** Patient has tried colchicine 0.6 mg tablets or capsules **[documentation required]**.

38. Subsequently, Cigna published a document entitled "Medication Coverage Changes 2024" in which Cigna stated that LODOCO® "will no longer be covered" because it is "being taken off the drug list." *See* Exhibit 23, p. 8. Cigna identified MITIGARE® (0.6 mg colchicine) as its covered alternative.

Cigna Healthcare Standard Prescription Drug List *(cont.)*

Medications that will no longer be covered because they're being taken off the drug list – and their covered alternatives[6] *(cont.)*

Date Change Starts	Medication Name	Drug Class	Generics and/or Preferred Medications
March 15th	JESDUVROQ	Miscellaneous	EPOGEN, PROCRIT, ARANESP, RETACRIT
	MOTPOLY XR	Seizure Disorders	lacosamide tablets, solution
	POKONZA	Nutritional/Dietary	potassium chloride tablets/capsules/ packets/solution, KLOR-CON tablet/packet, KLOR-CON M
March 1st	LODOCO	Blood Pressure/Heart Medications	colchicine 0.6mg, MITIGARE

39. MITIGARE® is indicated for prophylaxis of gout flares in adults. *See* Exhibit 24. It is not indicated or approved for cardiovascular events associated with atherosclerosis.

COUNT I

Infringement of U.S. Patent No. 10,206,891

40. Plaintiff incorporates and realleges all of the above paragraphs as though fully set forth herein.

41. The ’891 Patent is valid and enforceable.

42. Cigna has indirectly infringed, and continues to indirectly infringe, at least claims 1-5 of the ’891 Patent under 35 U.S.C. § 271(b) by inducing doctors to administer to patients 0.6 mg colchicine (e.g., MITIGARE®) to treat atherosclerotic diseases. This infringement is illustrated in the claim chart that is attached as Exhibit 25 and which is incorporated by reference as if fully set forth herein.

43. Cigna’s Formulary and the Formulary Exception Criteria require that a “[p]atient has tried colchicine 0.6 mg tablets or capsules” before being eligible to receive LODOCO®. On information and belief, doctors needing to provide access to LODOCO® to patients in need thereof have followed this prerequisite by administering colchicine 0.6 mg tablets or capsules as an off-label treatment for cardiovascular disease. Such doctors directly infringe the ’891 Patent. In addition, on information and belief, doctors with patients in need of LODOCO® have documented this off-label use as required by Cigna’s Formulary and Formulary Exception Criteria. Thus, Cigna intentionally and directly and/or indirectly instructs doctors with patients suffering from cardiovascular disease who need LODOCO® to infringe the ’891 Patent.

44. Cigna’s indirect infringement of the ’891 Patent is damaging and will continue to damage Plaintiff. Cigna actively, knowingly, and intentionally continues to induce infringement of the ’891 Patent through the creation and dissemination of its “Medication Coverage Changes 2024” document, which expressly states that Cigna no longer will reimburse for LODOCO® and that patients must use MITIGARE® as a “covered alternative.” Exhibit 23, at p. 8. This provides a strong financial incentive to doctors with patients suffering from cardiovascular disease who need LODOCO® to administer MITIGARE®, a gout medication which has not been approved for treatment of cardiovascular disease. Cigna has created this financial incentive despite being

informed by the January 4th Letter to Cigna Group that Plaintiff holds patents on the use of colchicine for atherosclerotic diseases. And knowledge of the Plaintiff's patents by Cigna Group can be imputed to Cigna Texas, CGLIC, and CHLIC, since these entities have worked together to defend against patent infringement lawsuits in this District in the past. *See*, *Alexsam v. Cigna*, 2-20-cv-0081 (EDTX, 2020). Furthermore doctors administering MITIGARE® to patients as a treatment for atherosclerotic disease directly infringe '891 Patent. Cigna acts with the knowledge and intent to encourage and induce third-party infringement through the creation and dissemination of the requirement to use MITIGARE® instead of LODOCO® its "Medication Coverage Changes 2024" document.

45. Cigna's continuing indirect infringement of the '891 Patent, despite having been notified about the Plaintiff's '891 Patent, will irreparably harm Plaintiff, and Cigna's indirect infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

46. Cigna's induced infringement of the '891 Patent is willful, justifying an award of increased damages and making this an exceptional case entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II

Infringement of U.S. Patent No. 10,265,281

47. Plaintiff incorporates and realleges all of the above paragraphs as though fully set forth herein.

48. The '281 Patent is valid and enforceable.

49. Cigna has indirectly infringed, and continues to indirectly infringe, at least claims 1-3, 5, 6, and 8 of the '281 Patent under 35 U.S.C. § 271(b) by inducing doctors to administer to patients 0.6 mg colchicine (e.g., MITIGARE®) to treat atherosclerotic diseases. This infringement

is illustrated in the claim chart that is attached as Exhibit 26 and which is incorporated by reference as if fully set forth herein.

50. Cigna's Formulary and the Formulary Exception Criteria require that a "[p]atient has tried colchicine 0.6 mg tablets or capsules" before becoming eligible to receive LODOCO®. On information and belief, doctors needing to provide access to LODOCO® to patients in need thereof have followed this prerequisite by administering colchicine 0.6 mg tablets or capsules as an off-label treatment for cardiovascular disease. Such doctors directly infringe the '281 Patent. In addition, on information and belief, doctors with patients in need of LODOCO® have documented this off-label use, as required by Cigna's Formulary and Formulary Exception Criteria. Thus, Cigna intentionally and directly and/or indirectly instructs doctors with patients suffering from cardiovascular disease who need LODOCO® to infringe the '281 Patent.

51. Cigna's indirect infringement of the '281 Patent is damaging and will continue to damage Plaintiff. Cigna actively, knowingly, and intentionally continues to induce infringement of the '281 Patent through the creation and dissemination of its "Medication Coverage Changes 2024" document, which expressly states that Cigna no longer will reimburse for LODOCO® and that patients must use MITIGARE® as a "covered alternative." Exhibit 23, at p. 8. This provides a strong financial incentive to doctors with patients suffering from cardiovascular disease who need LODOCO® to administer MITIGARE®, a gout medication which has not been approved for treatment of cardiovascular disease. Cigna has created this financial incentive despite being informed by the January 4th Letter to Cigna Group that Plaintiff holds patents on the use of colchicine for atherosclerotic diseases. And knowledge of the Plaintiff's patents by Cigna Group can be imputed to Cigna Texas, CGLIC, and CHLIC, since these entities have worked together to defend against patent infringement lawsuits in this District in the past. *See*, *Alexsam v. Cigna*, 2-

20-cv-0081 (EDTX, 2020). Furthermore, doctors administering MITIGARE® to patients as a treatment for atherosclerotic disease directly infringe '281 Patent. Cigna acts with the knowledge and intent to encourage and induce third-party infringement through the creation and dissemination of the requirement to use MITIGARE® instead of LODOCO® its "Medication Coverage Changes 2024" document.

52. Cigna's continuing indirect infringement of the '281 Patent, despite having been notified about the Plaintiff's '281 Patent, will irreparably harm Plaintiff, and Cigna's indirect infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

53. Cigna's induced infringement of the '281 Patent is willful, justifying an award of increased damages and making this an exceptional case entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III

Infringement of U.S. Patent No. 11,026,899

54. Plaintiff incorporates and realleges all of the above paragraphs as though fully set forth herein.

55. The '899 Patent is valid and enforceable.

56. Cigna has indirectly infringed, and continues to indirectly infringe, at least claims 1, 2, 4, 5, and 15 of the '899 Patent under 35 U.S.C. § 271(b) by inducing doctors to administer to patients 0.6 mg colchicine (e.g., MITIGARE®) to treat atherosclerotic diseases. This infringement is illustrated in the claim chart that is attached as Exhibit 27 and which is incorporated by reference as if fully set forth herein.

57. Cigna's Formulary and the Formulary Exception Criteria require that a "[p]atient has tried colchicine 0.6 mg tablets or capsules" before becoming eligible to receive LODOCO®. On information and belief, doctors needing to provide access to LODOCO® to patients in need

thereof have followed this prerequisite by administering colchicine 0.6 mg tablets or capsules as an off-label treatment for cardiovascular disease. Such doctors directly infringe the '899 Patent. In addition, on information and belief, doctors with patients in need of LODOCO® have documented this off-label use as required by Cigna's Formulary and Formulary Exception Criteria. Thus, Cigna intentionally and directly and/or indirectly instructs doctors with patients suffering from cardiovascular disease who LODOCO® to infringe the '899 Patent.

58. Cigna's indirect infringement of the '899 Patent is damaging and will continue to damage Plaintiff. Cigna actively, knowingly, and intentionally continues to induce infringement of the '899 Patent through the creation and dissemination of its "Medication Coverage Changes 2024" document, which expressly states that Cigna no longer will reimburse for LODOCO® and that patients must use MITIGARE® as a "covered alternative." Exhibit 23, at p. 8. This provides a strong financial incentive to doctors with patients suffering from cardiovascular disease who need LODOCO® to administer MITIGARE®, a gout medication which has not been approved for treatment of cardiovascular disease. Cigna has created this financial incentive despite being informed by the January 4th Letter to Cigna Group that Plaintiff holds patents on the use of colchicine for atherosclerotic diseases. And knowledge of the Plaintiff's patents by Cigna Group can be imputed to Cigna Texas, CGLIC, and CHLIC, since these entities have worked together to defend against patent infringement lawsuits in this District in the past. *See*, *Alexsam v. Cigna*, 2-20-cv-0081 (EDTX, 2020). Furthermore, doctors administering MITIGARE® to patients as a treatment for atherosclerotic disease directly infringe '899 Patent. Cigna acts with the knowledge and intent to encourage and induce third-party infringement through the creation and dissemination of the requirement to use MITIGARE® instead of LODOCO® its "Medication Coverage Changes 2024" document.

59. Cigna's continuing indirect infringement of the '899 Patent, despite having been notified about the Plaintiff's '899 Patent, will irreparably harm Plaintiff, and Cigna's indirect infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

60. Cigna's induced infringement of the '899 Patent is willful, justifying an award of increased damages and making this an exceptional case entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV

Infringement of U.S. Patent No. 11,026,900

61. Plaintiff incorporates and realleges all of the above paragraphs as though fully set forth herein.

62. The '900 Patent is valid and enforceable.

63. Cigna has indirectly infringed, and continues to indirectly infringe, at least claims 1, 2, 7, and 17 of the '900 Patent under 35 U.S.C. § 271(b) by inducing doctors to administer to patients 0.6 mg colchicine (e.g., MITIGARE®) to treat atherosclerotic diseases. This infringement is illustrated in the claim chart that is attached as Exhibit 28 and which is incorporated by reference as if fully set forth herein.

64. Cigna's Formulary and the Formulary Exception Criteria require that a "[p]atient has tried colchicine 0.6 mg tablets or capsules" before becoming eligible to receive LODOCO®. On information and belief, doctors needing to provide access to LODOCO® to patients in need thereof have followed this prerequisite by administering colchicine 0.6 mg tablets or capsules as an off-label treatment for cardiovascular disease. Such doctors directly infringe the '900 Patent. In addition, on information and belief, doctors with patients in need of LODOCO® have documented this off-label use as required by Cigna's Formulary and Formulary Exception Criteria. Thus, Cigna

intentionally and directly and/or indirectly instructs doctors with patients suffering from cardiovascular disease who need LODOCO® to infringe the ’900 Patent.

65. Cigna’s indirect infringement of the ’900 Patent is damaging and will continue to damage Plaintiffs. Cigna actively, knowingly, and intentionally continues to induce infringement of the ’ 900 Patent through the creation and dissemination of its “Medication Coverage Changes 2024” document, which expressly states that Cigna no longer will reimburse for LODOCO® and that patients must use MITIGARE® as a “covered alternative.” Exhibit 23, at p. 8. This provides a strong financial incentive to doctors with patients suffering from cardiovascular disease who need LODOCO® to administer MITIGARE®, a gout medication which has not been approved for treatment of cardiovascular disease. Cigna has created this financial incentive despite being informed by the January 4th Letter to Cigna Group that Plaintiff holds patents on the use of colchicine for atherosclerotic diseases. And knowledge of the Plaintiff’s patents by Cigna Group can be imputed to Cigna Texas, CGLIC, and CHLIC, since these entities have worked together to defend against patent infringement lawsuits in this District in the past. *See*, *Alexsam v. Cigna*, 2-20-cv-0081 (EDTX, 2020). Furthermore, doctors administering MITIGARE® to patients as a treatment for atherosclerotic disease directly infringe the ’900 Patent. Cigna acts with the knowledge and intent to encourage and induce third-party infringement through the creation and dissemination of the requirement to use MITIGARE® instead of LODOCO® its “Medication Coverage Changes 2024” document.

66. Cigna’s continuing indirect infringement of the ’900 Patent, despite having been notified about the Plaintiff’s ’900 Patent, will irreparably harm Plaintiff, and Cigna’s indirect infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

67. Cigna's induced infringement of the ' 900 Patent is willful, justifying an award of increased damages and making this an exceptional case entitling Plaintiff to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT V

Infringement of U.S. Patent No. 11,026,901

68. Plaintiff incorporates and realleges all of the above paragraphs as though fully set forth herein.

69. The '901 Patent is valid and enforceable.

70. Cigna has indirectly infringed, and continues to indirectly infringe, at least claims 1, 2, 10, and 11 of the '901 Patent under 35 U.S.C. § 271(b) by inducing doctors to administer to patients 0.6 mg colchicine (e.g., MITIGARE®) to treat atherosclerotic diseases. This infringement is illustrated in the claim chart that is attached as Exhibit 29 and which is incorporated by reference as if fully set forth herein.

71. Cigna's Formulary and the Formulary Exception Criteria require that a "[p]atient has tried colchicine 0.6 mg tablets or capsules" before becoming eligible to receive LODOCO®. On information and belief, doctors needing to provide access to LODOCO® to patients in need thereof have followed this prerequisite by administering colchicine 0.6 mg tablets or capsules as an off-label treatment for cardiovascular disease. Such doctors directly infringe the '901 Patent. In addition, on information and belief, doctors with patients in need of LODOCO® have documented this off-label use as required by Cigna's Formulary and Formulary Exception Criteria. Thus, Cigna intentionally and directly and/or indirectly instructs doctors with patients suffering from cardiovascular disease who need LODOCO® to infringe the '901 Patent.

72. Cigna's indirect infringement of the '901 Patent is damaging and will continue to damage Plaintiffs. Cigna actively, knowingly, and intentionally continues to induce infringement

of the ’901 Patent through the creation and dissemination of its “Medication Coverage Changes 2024” document, which expressly states that Cigna no longer will reimburse for LODOCO® and that patients must use MITIGARE® as a “covered alternative.” Exhibit 23, at p. 8. This provides a strong financial incentive to doctors with patients suffering from cardiovascular disease who need LODOCO® to administer MITIGARE®, a gout medication which has not been approved for treatment of cardiovascular disease. Cigna has created this financial incentive despite being informed by the January 4th Letter to Cigna Group that Plaintiff holds patents on the use of colchicine for atherosclerotic diseases. And knowledge of the Plaintiff’s patents by Cigna Group can be imputed to Cigna Texas, CGLIC, and CHLIC, since these entities have worked together to defend against patent infringement lawsuits in this District in the past. *See*, *Alexsam v. Cigna*, 2-20-cv-0081 (EDTX, 2020). Furthermore, doctors administering MITIGARE® to patients as a treatment for atherosclerotic disease directly infringe the ’901 Patent. Cigna acts with the knowledge and intent to encourage and induce third-party infringement through the creation and dissemination of the requirement to use MITIGARE® instead of LODOCO® its “Medication Coverage Changes 2024” document.

73. Cigna’s continuing indirect infringement of the ’901 Patent, despite having been notified about the Plaintiff’s ’901 Patent, will irreparably harm Plaintiff, and Cigna’s indirect infringement will continue unless enjoined by this Court pursuant to 35 U.S.C. § 283.

74. Cigna’s induced infringement of the ’901 Patent is willful, justifying an award of increased damages and making this an exceptional case entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment against Cigna, granting Plaintiff the following relief:

A. A judgment holding Cigna liable for indirect infringement of the Patents-in-Suit;

B. Damages resulting from Cigna's induced infringement of the Patents-in-Suit in an amount to be proven at trial, but no less than a reasonable royalty, such damages to be increased up to three times as a result of Cigna's willful infringement, together with pre-judgment and post-judgment interest;

C. An injunction permanently enjoining Cigna under 35 U.S.C. § 283 from inducing infringement of the Patents-in-Suit, including by specifically prohibiting Cigna from requiring patients seeking reimbursement for treatment of their atherosclerotic disease with colchicine to use any other colchicine formulation besides LODOCO®;

E. A judgment holding this to be an exceptional case, and an award to Plaintiff of its attorneys' fees and costs pursuant to 35 U.S.C. § 285; and

F. Such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby demands a trial by jury on all issues so triable.

April 8, 2024

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