UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

TIMOTHY DIXON, Plaintiff, vs. TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC.; Defendants.	Case No. 1:20-cv-2325 JURY TRIAL DEMANDED

COMPLAINT

NOW COMES Plaintiff, TIMOTHY DIXON, by and through his attorneys, SALIM-BEASLEY LLC, and respectfully files this Complaint at Law against the Defendants, TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC. (hereinafter collectively referred to as, "Defendants"), and states as follows:

NATURE OF THE CASE

1. This action is brought by Plaintiff, TIMOTHY DIXON, who was prescribed Uloric® (febuxostat) (hereinafter referred to as "Uloric"), for the treatment of his medically diagnosed condition, gout.

2. Defendants designed, research, manufactured, tested, advertised, promoted, marketed, sold and distributed Uloric in the United States.

3. Defendants negligently represented to the medical and healthcare community, including Plaintiff's prescribing doctor, the Food and Drug Administration (hereinafter referred to

as the "FDA"), to Plaintiff and the public in general that Uloric had been tested and was found to be safe and effective for its indicated uses.

4. Defendants concealed their knowledge of Uloric's defects from Plaintiff, the FDA, the public in general, and the medical community, including Plaintiff's prescribing doctor.

5. Specifically, several unlabeled fatal or life-threatening adverse reactions have been known by Defendants to occur as a result of Uloric's interaction with other drugs commonly used by the same patient population. Notwithstanding, this drug's package insert warnings encourage their co-administration with other commonly used drugs, deny the drug interaction or downplay the interaction. Post-marketing adverse events are consistent with the pre-approval data that went unwarned. Millions of patients, including Plaintiff, are placed at risk and harmed as a result of this misleading conduct as doctors prescribe this drug oblivious to the dangerous interactions they have with drugs that their patients are already taking.

6. Acutely aware of its precarious marketing posture relative to a cheaper, safer, established gout treatment, Defendants resorted to deceitful reporting relative to (1) fatal drug interactions with auto-immune drug treatments, (2) severe and fatal bleeding due to warfarin interactions and (3) renal failures, each of which are related to prevalent co-morbidities for gout patients. On each of these points, Defendants knowingly and falsely claimed, and its labeling indicated, a marketing advantage over Allopurinol. In order to obtain and retain government payment for Uloric gout treatment, the company evaded accurate reporting of the adverse events related to these claimed marketing superiorities. The evidence demonstrates Defendants knowingly hid and/or minimized these risks for pure economic reasons.

7. Approved for U.S. sales in February 2009, Uloric has been heavily promoted in television direct to consumer advertising. Defendants project Uloric to be a billion dollar a year

drug within the foreseeable future. As part of its plan to achieve this level of sales, Defendants have under-reported serious adverse events related to Uloric use, some of which required expedited 15-day reporting to the FDA, but were not so reported.

8. As a result of the foregoing acts and omissions, Plaintiff has suffered serious and dangerous side effects including heart attack.

PARTIES AND JURISDICTION

9. At all times relevant hereto, Plaintiff, TIMOTHY DIXON, was and is a citizen and resident of Blount County, in the State of Tennessee.

10. Upon information and belief, Plaintiff consumed and regularly used Defendants' Uloric® (febuxostat) product. As a result of his use of Defendants' Uloric product, Plaintiff suffered from severe physical, economic and emotional injuries, including but not limited to heart attack.

11. Defendant, Takeda Pharmaceutical Company Limited (hereinafter "TPC"), is a Japanese corporation, having its corporate headquarters and principal place of business in Osaka Japan. TPC is the largest pharmaceutical company in Japan. According to its 2009 annual reports, TPC's annual sales exceeded $15 billion.

12. Defendant, Takeda Pharmaceuticals U.S.A., Inc. (hereinafter "TPUSA."), now is, and at all times relevant to this action was, a wholly owned U.S. subsidiary of TPC. TPUSA is organized under the laws of Delaware and has its principal place of business located at One Takeda Parkway, Deerfield, Illinois 60015, USA. TPUSA is one of the 15 largest pharmaceutical companies in the United States. According to its annual report, TPUSA's 2008 annual sales were reported to be in excess of five billion dollars. Much of Takeda's recent and current pharmaceutical sales are derived from Uloric.

13. Defendant, Takeda Pharmaceuticals America, Inc. (hereinafter "TPA."), now is, and at all times relevant to this action was, a wholly owned U.S. subsidiary of TPUSA and a U.S. commercial organization of TPC. TPA is organized under the laws of Delaware and has its principal place of business located at One Takeda Parkway, Deerfield, Illinois 60015.

14. TPC, TPUSA and TPA will be collectively referred to as "Defendants."

15. Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold in the United States the drug brand name, Uloric, which is used to lower blood uric acid levels in adults with gout.

16. Defendants are currently transacting business from within Illinois and Cook County, Illinois, at least by maintaining offices and employees in Illinois, making and shipping into Illinois, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products, including Uloric in Illinois and Cook County, Illinois. Defendants derive substantial revenue from interstate and or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Illinois and this Judicial District.

17. Defendants have conducted business and derived substantial revenue from within Illinois and Cook County, Illinois, and has sufficient minimum contacts and intentionally avails itself of the Illinois market so as to render the exercise of jurisdiction over it by the Illinois courts consistent with the traditional notions of fair play and substantial justice.

18. Defendants, with respect to the product at issue in the case at bar, have made or performed contracts or promises substantially connected to Cook County, Illinois.

19. Therefore, this Court may exercise jurisdiction over Defendants under the laws of Illinois, the Illinois Constitution, and the Constitution of the United States.

20. Venue is proper in this Court as a substantial part of the counts giving rise to this complaint occurred in Cook County, Illinois.

UNDERLYING COMMON FACTS

21. At all relevant times, Defendants directly or through their agents, apparent agents, servants or employees designed, manufactured, marketed, advertised, distributed, promoted, and sold the prescription product, Uloric® (febuxostat), which is used to lower blood uric acid levels in adults with gout.

22. Uloric is a xanthine oxidase inhibitor, which contains the active ingredient, febuxostat. Febuxostat is a nonpurine inhibitor of xanthine oxidase, and it is designed for patients with hyperuricemia and gout, and also to patients who have exhibited sensitivities to Allopurinol. Allopurinol was the first line drug in the treatment of hyperuricemia and gout. Since 1946, Allopurinol has been used as a xanthine oxidase inhibitor for treatment of hyperuricemia and gout. However, in 2009, the FDA approved febuxostat as an alternative therapy for hyperuricemia and gout.

23. Hyperuricemia is defined as high levels of uric acid in the blood. In most cases, where elevated serum uric acid is noted without inflammatory response, patients are asymptomatic and treatment is not advised. However, in the cases where painful inflammation around the crystallized urate in the joint has already formed, the patient is generally diagnosed with gout and treatment is indicated.

24. Gout is an inflammatory arthritic disease with growing incidence. Gout was originally associated with individuals consuming a high fat diet, purine rich foods and a relatively inactive lifestyle, but it is now considered a metabolic disorder and is linked to a variety of other disease states. In recent years, gout has been implicated in conditions such as hypertension, obesity, kidney disease, hyperlipidemia, metabolic syndrome and cardiovascular disease. Most

patients exhibit elevated serum uric acid levels for years before symptoms arise. Gout is most commonly observed in males over fifty years of age.

25. Defendants submitted its New Drug Application for Uloric to the Food and Drug Administration (hereinafter "FDA"), and the FDA eventually approved of Uloric in February 2009. The FDA's approval of the New Drug Application allowed Defendants to legally market and sell Uloric in the United States to patients, including Medicaid, Medicare and TRICARE patients. As part of the New Drug Application process, Defendants via its execution of various forms, including but not limited to FDA Form 35h, expressly and impliedly certified that it would comply with all adverse event reporting requirements, including the reporting requirements delineated in 21 C.F.R. § 314.80. Accordingly, compliance with 21 C.F.R. § 314.80 and the adverse event reporting obligations was a condition precedent to obtaining and maintaining the FDA's approval to promote and sell Uloric to consumers, including consumers on governmental assistance.

26. Contrary to the adverse event reporting promises and certifications that Defendants had given to the FDA, Defendants initiated a system to intentionally conceal a substantial number of adverse event reports and thus had no intention of complying with its certifications and promises.

27. In order to dominate the gout drug markets, to increase the sales of Uloric and to facilitate the continued reimbursement from Government Healthcare Programs for claims made by providers for Uloric, Defendants misrepresented and/or concealed material facts regarding adverse events attributable to Uloric.

28. Defendants suppressed knowledge of, and failed to submit full and complete Periodic Adverse Drug Experience Reports to the FDA, which would have shown that there were

increased risks from Uloric associated with Drug/Drug Interaction while treating gout. Such conduct by Defendants deviated from the duties and conduct of a responsible pharmaceutical manufacturer and demonstrated a failure to ensure its own minimal compliance with requirements of the Federal Food Drug and Cosmetic Act.

29. Defendants were required to submit "Periodic Adverse Drug Experience Reports." Defendants were required to submit each adverse drug experience not reported under paragraph (c)(1)(I) of section 314.80 at quarterly intervals, for three years from the date of approval of Uloric, and then at annual intervals.

30. Defendants submitted false Periodic Adverse Drug Experience Reports to the FDA. Defendants did so because it failed to include numerous Drug/Drug Interaction adverse events as serious adverse events.

31. Two conflicting Warfarin-Uloric study results submitted by Defendants to the FDA in 2005 and 2008 indicate Defendants' misconduct. In a correspondence dated October 14, 2005, regarding Defendant's 2005 Warfarin drug interaction study, FDA's medical reviewer, Dr. Robert J. Meyer, concluded that:

> A significant concern exists due to the finding that two subjects died as a result of retroperitoneal hemorrhages while being treated with Uloric, both of whom were receiving Warfarin as well. Additional hemorrhagic events were also noted in the safety database. We do not agree with your conclusion that there were no drug-drug interaction with Warfarin in the clinical pharmacology study, due to our conclusion that the drug-drug interaction study with Warfarin was inadequate to allow for definitive conclusions. The removal of subjects with an increased INR from the final analysis in the Warfarin drug-drug interaction trial was problematic. In addition, there were reports of increased INR values in the clinical database in subjects receiving concomitant treatment with Uloric and Warfarin.

31. Essentially, Dr. Meyer points out that co-administration of Uloric with a blood thinner like Warfarin appeared to alter Warfarin's plasma concentration resulting in two fatal hemorrhagic events and many other serious hemorrhagic events during Defendants' clinical trials,

and that Defendants commenced screening out patients with high INR (international normalized ratio) levels, a pre-cursor signal for hemorrhagic events. By screening these people out, Takeda masked the drug-drug interaction with Warfarin.

32. Such an interaction was to be expected since the parallel gout treatment, Allopurinol, carried a drug interaction warning for Warfarin, and vice versa. This is included in the package insert and warnings for Allopurinol and Warfarin. Both Allopurinol and Uloric are members of a class of drugs used to treat elevated uric acid levels in blood plasma that leads to gout; hence, they are gout treatment agents. Both accomplish uric acid reduction by inhibiting the enzyme xanthine oxidase. Xanthine oxidase promotes the production of uric acid, so its inhibition lowers uric acid levels in plasma. Thus, xanthine oxidase inhibitors have become a common treatment for treating illnesses, like gout, caused by elevated plasma uric acid. However, as xanthine oxidase inhibitors, both Uloric and Allopurinol affect other drugs that are metabolized by the xanthine oxidase enzyme, such as the immune suppressants Imuran and Purinethol. Continued ingestion of a xanthine oxidase inhibitor while also taking a drug metabolized by the xanthine oxidase enzyme results in elevated, and possibly toxic, levels of the drug not getting metabolized. This is due to the reduced xanthine oxidase available to break it down (metabolize it) and excrete it. Thus, it should be anticipated that Allopurinol's interaction with drugs metabolized by xanthine oxidase would be echoed with Uloric.

33. Warfarin shares the same metabolism pathway CYP 450 isoform 2C9 with Allopurinol, and Allopurinol inhibits the metabolism of S-isomer, a subtype of 2C9 that prolongs the prothrombin that leads to hemorrhages. Warfarin's package insert warnings include drug interaction with "Gout Treatment Agents," referring to the class of drugs that reduce plasma uric acid levels. Thus, the occurrence of two fatal hemorrhaging events in the early Uloric clinical trials

amongst patients taking both Uloric and Warfarin was a big red flag indicating the class effect shown by Allopurinol was also occurring with Uloric. The mechanism was the same and well understood. Therefore, Dr. Meyer conditioned Uloric's approval on a follow-up evaluation to rule out an Uloric-Warfarin adverse drug interaction resulting in hemorrhages: "We are withholding labeling comments pending the resolution of the above deficiencies."

34. The FDA's Clinical Review Team Leader, Dr. Schiffenbauer, concurred with Dr. Meyer's concerns in his July 3, 2006 Clinical Review, referring to the two cases of retroperitoneal hemorrhage in a database that size as "disturbing (most likely related to changes in INR in patients on Warfarin)." Summarizing other adverse events like an 8:0 ratio of deaths for Uloric versus Allopurinol, 7:0 for strokes, 12:1 myocardial infarctions, 4:0 renal failures, 8:1 congestive heart failures, etc., Dr. Schiffenbauer concluded, "the risk/benefit analysis is not favorable for this drug at this time."

35. Surprisingly, in the subsequent February 2009 Uloric NDA review summary, a different group of FDA reviewers wrote: "The sponsor submitted their new Warfarin-febuxostat [Uloric] interaction study in this response. The review team evaluated that study and concurred with the sponsor that it demonstrated that there was no interaction of multiple 80 mg doses of febuxostat with Warfarin."

36. The 2008 study results for Uloric's interaction with Warfarin, presented in response to Dr. Meyer's demand, seem incongruous. Per Dr. Meyer's review of the first phase three clinical trial database, there were two deaths from hemorrhage, due to the much higher plasma concentration of Warfarin, and significant bleeding events reported from both Uloric and Allopurinol groups where all these patients had co-administered with Warfarin. Dr. Meyer further indicated in his review on 10/24/2005 that Takeda's drug interaction study was problematic due

to removal of subjects with an increased INR (international normalized ratio) from the final analysis. Additional clinical trial data also disclosed increased INR indicating a bleeding risk caused by Warfarin. However, the second study showed no interaction at all. Moreover, a review of the FDA's AERS post approval shows the following:

3 Rectal hemorrhage co-administered with Coumadin

2 Stroke co-administered with Coumadin

4 Hematuria co-administered with Coumadin

1 Upper GI hemorrhage co-administered with Coumadin

3 PT prolongation (Prothrombin Time Prolonged) co-administered with Coumadin

2 Gastric ulcer co-administered with Coumadin

37. Allopurinol interacts with most commonly prescribed medications, and since Uloric is in the same class of drugs as Allopurinol, it should be expected to have the same interactions.

38. Most interactions with Allopurinol were CYP450, both induction and inhibition. As discussed above, the interaction with Warfarin appears to be on isoform 2C9, which inhibits Warfarin's metabolism, then elevates the Warfarin's plasma concentration. Warfarin is an NTR (narrow therapeutic range) drug, and very small changes in plasma concentration would result in bleeding, and this was the FDA's major safety concern. According to Relator Helen Ge, M.D., a former contract physician of drug safety with Defendants, Uloric acts as an inhibitor in the CYP 450 metabolization process, interfering with the other drug's metabolism, resulting in the higher plasma concentration of co-administered drugs that share the same enzyme. When Uloric inhibited the 1A2 enzyme on theophylline and methadone, and 2C8 enzyme with Imuran and MTX, it resulted in the deaths reported in Dr. Ge's original Uloric Disclosure Memorandum.

39. Consequently, Defendants should have done studies addressing at least six or seven major enzymes, including 1A2, 2C8 and 2C9 on both induction and inhibition. Defendants' Uloric should have had clear documentation in the label for safe use, but Defendant failed to do such testing, leading to the deficiencies indicated in both Drs. Meyer and Schiffenbauer's reviews.

40. Uloric's interaction with other drugs, including Warfarin (Coumadin), was the subject of deficiencies observed by the FDA in Defendants' Uloric NDA. Instead of properly addressing those concerns, Defendants evaded the FDA's recommendations and proceeded to market Uloric without sufficient drug interaction warnings or studies. This has resulted in Warfarin hemorrhagic bleeding incidents and a fatal methadone interaction. The pre-existing drug-drug interaction problems during the NDA may explain some of the bizarre machinations undertaken to avoid reporting post-marketing Uloric drug interactions.

Mislabeled Recommendation to Renal Impairment Patients to Use Uloric

41. Additionally, Uloric's original package insert at section 8.6 stated that Uloric could be used in the renal impairment patient population with mild or moderate creatinine clearance decrease. There was insufficient basis to support this statement. The Uloric NDA disclosed three or four renal impairments for Uloric and two for Allopurinol. The PK study for renal function only involved about 20 patients at the most, which was not enough data to support the claim that Uloric can be used in mild or moderate renal impairment patient population, especially since several million patients comprise this population. Subsequent Uloric phase three trials may have excluded patients who had mild or moderate renal function impairments, so that Defendants would be able to build a better safety profile to achieve approval.

42. Once Uloric got on the market with exposure to the general patient population, there were ten acute renal failures reported in less than two years. Dr. Ge's observation while working

for Defendants was different than that suggested by the label since she saw frequent Uloric related renal failure cases. Typical of those was an incident wherein a retired physician switched his wife from Allopurinol to Uloric, and his wife's renal function got worse (the creatinine clearance dropped from middle 50 to less than 20/min), and he had to put her on dialysis.

43. Notwithstanding, Uloric's present advertising and website continue to assert that Uloric is superior to Allopurinol because "Patients with mild to moderate kidney problems do not have to take a lower dose" of Uloric, whereas "Patients with kidney problems have to take a lower dose" of Allopurinol." There is no reference to the ten acute renal failures in the Uloric web-ad, nor in the Uloric label.

44. There are serious unreasonable health risks associated with prescription drugs whose sponsors fail to abide by FDS's ADE reporting requirements. Defendants' drug Uloric presents and constitutes an unreasonable risk of danger and injury in the following respects:

a) Uloric was not properly manufactured;

b) Uloric was defectively designed;

c) Uloric did not perform as safely as an ordinary consumer/patient would expect;

d) Uloric was inadequate or insufficient to maintain its integrity during normal use by the consumer/patient; and

e) Such further and additional defects as discovery and the evidence reveals.

45. Upon information and belief, in 2011, Plaintiff's treating medical physician prescribed Uloric to Plaintiff due to Plaintiff's high blood uric acid levels and his medically diagnosed gout condition. Defendants represented Uloric to be an appropriate and suitable product for such purposes.

46. On or about April 2019, Plaintiff was admitted to the Emergency Room at University of Tennessee Medical Center.

47. Plaintiff was discharged from University of Tennessee Medical Center and the treating physician diagnosed Plaintiff with a heart attack.

48. Upon information and belief, Plaintiff discontinued his use of Uloric in 2019.

49. As a result of Defendants' actions and inactions, Plaintiff was injured due to Uloric, which caused Plaintiff various injuries and damages. Plaintiff accordingly seeks damages associated with these injuries.

50. At all times herein mentioned, Defendants knew or, in the exercise of reasonable care, should have known that Uloric was not properly manufactured, tested, inspected, packaged, labeled, distributed, marketed, examined, sold, supplied, prepared and/or provided with proper warnings, was not suitable for the purpose it was intended and was unreasonably likely to injure the products' users.

51. Defendants ignored reports from patients and health care providers throughout the United States of Uloric's failure to perform as intended, which led to the severe and debilitating injuries suffered by Plaintiff and numerous other patients. Rather than doing adequate testing to determine the cause of these injuries or rule out Uloric's design as the cause of the injuries, Defendants continued to market Uloric as a safer and more effective prescriptive drug as compared to other available alternative treatment for hyperuricemia and gout.

52. Defendants did not timely or adequately apprise the public and physicians of the adverse effect or defects in Uloric, despite Defendants' knowledge that it had failed due to the described defects.

53. Defendants' Uloric was at all times utilized and prescribed in a manner foreseeable to Defendants, as Defendants generated the instructions for use for Plaintiff to take Uloric.

54. Plaintiff and Plaintiff's physicians foreseeably used the Defendants' Uloric, and did not misuse, or alter the Uloric in an unforeseeable manner.

55. Feasible and suitable alternative products and prescribed medications, as well as suitable alternative treatment of hyperuricemia and gout have existed at all times relevant as compared to the Defendants' Uloric.

56. Despite their knowledge of the dangerous side effects that can result from Uloric use, Defendants refused to warn patients, physicians and the medical community about the risks.

57. Through their affirmative misrepresentations and omissions, Defendants actively concealed from Plaintiff and his physicians the true and significant risks associated with Uloric consumption.

58. Contrary to Defendants' representations, the Uloric has a high rate of injury and complications associated with its intended use; the product fails to perform as intended resulting in acute blood loss, volume overload and acute renal (kidney) failure.

59. Defendants' Uloric product, which was prescribed to Plaintiff, was in the same or substantially similar condition as when it left the possession of the Defendants and in the condition directed by and expected by the Defendants.

60. Defendants advertised, promoted, marketed, sold, and distributed Uloric as a safe product when Defendants knew or should have known Uloric was not safe for its intended purposes and that Uloric could cause serious medical problems.

61. Defendants had sole access to material facts concerning the defective nature of the Uloric and its propensity to cause serious and dangerous side effects.

62. Defendants under reported information about the propensity of Uloric to fail, cause injury and complications, and Defendants have made unfounded representations regarding the efficacy and safety of the Uloric.

63. In reliance on Defendants' representations, Plaintiff's doctors were induced to, and did prescribe the Defendants' Uloric.

64. As a result of Defendants' actions, Plaintiff and his physicians were unaware, and could not have reasonably known or have learned through reasonable diligence that Plaintiff would be exposed to the risks identified in this Complaint and that those risks were the direct and proximate result of Defendants' conduct.

65. As a direct result of being prescribed and consuming Uloric, Plaintiff has been permanently and severely injured, having suffered serious consequences.

66. As a direct and proximate cause of Defendants' conduct, Plaintiff has suffered injuries and will require continual monitoring and future ongoing medical care and treatment. Accordingly, Plaintiff will incur future medical costs related to Uloric.

67. Plaintiff, as a direct and proximate result of Uloric, suffered severe mental and physical pain and suffering and has and will sustain permanent injuries and emotional distress, along with economic loss due to medical expenses and living-related expenses due to his new lifestyle.

68. Plaintiff's physicians would not have prescribed Uloric had Defendants properly disclosed the risks associated with its use.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

69. Defendants failed to disclose a known defect and affirmatively misrepresented that Uloric was safe for its intended use. Further, Defendant actively concealed the true risks

associated with the use of Uloric. Neither Plaintiff nor Plaintiff's prescribing physician had knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of Defendant's concealment of and misrepresentations regarding the true risks associated with Uloric, Plaintiff could not have reasonably discovered Defendants' wrongdoing at any time prior to the commencement of this action.

70. Thus, because Defendants fraudulently concealed the defective nature of Uloric and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendants are estopped from relying on any statute of limitations.

71. Additionally, and alternatively, Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Uloric caused the appreciable harm sustained by Plaintiff. Plaintiff did not have actual or constructive knowledge of facts indicating to a reasonable person that Plaintiff was the victim of a tort. Plaintiff was unaware of the facts upon which a cause of action rests until less than the applicable limitations period prior to the filing of this action. Plaintiff's lack of knowledge was not willful, negligent, or unreasonable.

COUNT I
STRICT LIABILITY AGAINST TAKEDA PHARMACEUTICAL COMPANY LIMITED

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of Defendant, TAKEDA PHARMACEUTICAL COMPANY LIMITED ("TPC"), states as follows:

1-71. For paragraphs 1-71 of Count I, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. At all times relevant hereto, TPC manufactured, designed, distributed, and/or sold Uloric.

73. At all times relevant hereto, the dangerous propensities of Uloric were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

74. The Uloric product as distributed by Defendants was a defective and unreasonably dangerous product, as Defendants failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for its ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Uloric to lower blood uric acid levels in adults with gout.

75. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician that Defendants' Uloric product was designed and/or manufactured in a way that could cause injuries and damages, including lasting and permanent injuries. Defendants further failed to inform and/or warn Plaintiff and Plaintiff's treating physician with respect to the selection of appropriate candidates to receive Defendants' Uloric product.

76. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician as to the risks of the Defendants' Uloric product. To the contrary, Defendants withheld information from Plaintiff and Plaintiff's physician regarding the true risks related to prescribing the Uloric product.

77. The warnings that were given by Defendants failed to properly warn the medical community and patients of the increased risk of physical injuries including, but not limited to, dyspnea, acute blood loss, volume overload, acute renal (kidney) failure, and acute gouty flare, resulting in pain and other serious injuries and side effects.

78. The Uloric product, as distributed by Defendants, was dangerous in design at the time it left the Defendants' control.

79. At the time the Uloric product left Defendants' control, there existed feasible and suitable alternative design for the treatment of hyperuricemia and gout that was capable of preventing Plaintiff's damages.

80. When compared to other feasible alternatives, the Uloric product greatly results in a much higher risk of dyspnea, acute blood loss, volume overload, acute renal (kidney) failure, and acute gouty flare. Other feasible alternative designs exist which do not present the same frequency and severity of risks.

81. At all times relevant to this action, Defendants manufactured, supplied, distributed, and/or sold Uloric in a defective and dangerous condition, as described above, to Plaintiff.

82. Uloric was defective in manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical manufacturer.

83. The Uloric product prescribed and ingested by Plaintiff was unreasonably dangerous in construction and composition because it deviated in a material way from the Defendants' specifications and performance standards for the product.

84. The dangerous, defective conditions of Uloric were not known, knowable, and / or reasonably visible to Plaintiff and /or Plaintiff's physician or discoverable upon reasonable examination.

85. As a direct, foreseeable and proximate result of Defendants' defective Uloric product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as

referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against Defendant, TPC, in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT II
NEGLIGENCE AGAINST TAKEDA PHARMACEUTICAL COMPANY LIMITED

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICAL COMPANY LIMITED ("TPC"), states as follows:

1-71. For paragraphs 1-71 of Count II, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. At all times relevant hereto, it was the duty of TPC to use reasonable care in the manufacturing, design, distribution, and/or sale of Uloric.

73. In disregard of its aforesaid duty, TPC was guilty of one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Uloric without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Uloric while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Uloric;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Uloric was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Uloric was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative hyperuricemia and gout products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Uloric;

g. Advertising, marketing, and recommending the use of Uloric, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Uloric;

h. Representing that Uloric was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative hyperuricemia and gout products were available for use for the purpose for which Uloric was manufactured;

j. Continuing to manufacture and sell Uloric with the knowledge that Uloric was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Uloric so as to avoid the risk of serious harm associated with the use of Uloric;

l. Failing to design and manufacture Uloric so as to ensure the drug was at least as safe and effective as other similar products;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Uloric and that use of Uloric created a high risk of severe injuries;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Uloric.

74. As a direct and proximate result of one or more of the above-stated negligent acts by Defendant, TPC, Plaintiff, TIMOTHY DIXON, suffered grievous bodily injuries and

consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against TPC, in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT III
BREACH OF EXPRESS WARRANTY AGAINST TAKEDA PHARMACEUTICAL COMPANY LIMITED

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICAL COMPANY LIMITED ("TPC"), states as follows:

1-71. For paragraphs 1-71 of Count III, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. Uloric was unreasonably dangerous because it did not conform to express warranties.

73. In the course of business, Defendants designed, manufactured and sold Uloric to be used to lower blood uric acid levels in adults with gout.

74. In selling Uloric to Plaintiff's prescribing physician, the Defendants made representations to the physician about Uloric, affirming that Uloric possessed specific characteristics and would meet a specified level of performance; specifically, that Uloric was appropriate and suitable for the purposes to lower blood uric acid levels in adults with gout.

75. In advertising, marketing and otherwise promoting Defendants' Uloric to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that Uloric was safe for use and reasonably fit for their intended purposes. In advertising, marketing and

otherwise promoting Defendants' Uloric, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to prescribe Uloric to their patients.

76. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to Uloric, including, but not limited to, the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that Uloric was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Uloric;

b. Defendants represented to Plaintiff, his physicians and healthcare providers that Uloric was as safe and/or safer than other alternative products then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that Uloric was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff, his physicians and healthcare providers that Uloric was more efficacious than other alternative product, meanwhile concealing information regarding the true efficacy of Uloric.

77. Plaintiff and Plaintiff's physician relied upon Defendants express warranties.

78. Defendants' express warranties induced the Plaintiff's physician to use Uloric to lower blood uric acid levels in Plaintiff, who possessed gout.

79. The Plaintiff's damage was proximately caused because the express warranties made about Uloric were untrue.

80. As a direct and proximate result of one or more of the above-stated breach of warranties by Defendant, TPC, Plaintiff, TIMOTHY DIXON, suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against Defendant, TPC, in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT IV
BREACH OF IMPLIED WARRANTIES AGAINST TAKEDA PHARMACEUTICAL COMPANY LIMITED

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICAL COMPANY LIMITED ("TPC"), states as follows:

1-71. For paragraphs 1-71 of Count IV, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. Uloric was unreasonably dangerous because it did not conform to implied warranties.

73. At all relevant and material times, Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and otherwise placed in to the stream of commerce Uloric.

74. Defendants impliedly warranted that Uloric was merchantable and was fit for the ordinary purposes for which it was intended.

75. Defendants impliedly warranted that their Product was of merchantable quality, safe and fit for the intended use to lower blood uric acid levels in adults with gout and that it was properly and adequately tested prior to being placed in the stream of commerce.

76. When Uloric was prescribed to the Plaintiff, it was being used for the ordinary purposes for which it was intended.

77. Defendants intended that Uloric be prescribed and taken by Plaintiff for the purposes and in the manner that Plaintiff's physician prescribed it, in accordance with the product specifications provided by Defendants.

78. Defendants were aware that consumers, such as the Plaintiff, would be prescribed with Uloric by their treating physicians in accordance with the product specifications provided by Defendants.

79. Plaintiff was a foreseeable user of Defendants' Uloric and was in privity with Defendants.

80. Defendants breached implied warranties with respect to Uloric, including, but not limited to the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Uloric was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Defendants' Uloric;

b. Defendants represented to Plaintiff, Plaintiff's physicians and healthcare providers that the Defendants' Uloric was safe, as safe as and/or safer than other alternative medications, meanwhile Defendants fraudulently concealed information, which demonstrated that Uloric was not safe, as safe as or safer than alternatives and other products available on the market; and

c. Defendants represented to Plaintiff, Plaintiff's physicians and healthcare providers that the Defendants' Uloric was more efficacious than other alternative products and/or medications, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Defendants' Uloric.

81. The Plaintiff individually and/or by and through his physician, relied upon Defendants' implied warranties in consenting to be prescribed and to have ingested Uloric.

82. In reliance upon Defendants' implied warranties, Plaintiff's prescribing physician used Defendants' Uloric to treat Plaintiff in the foreseeable manner normally intended,

recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

83. Defendants breached their implied warranties to Plaintiff because Defendants' Uloric was not of merchantable quality, safe and fit for its intended use, as warranted, nor was it adequately tested prior to being placed in the stream of commerce.

84. Defendants' breach of their implied warranties resulted in Plaintiff consuming Defendants' unreasonably dangerous and defective product and placing said Plaintiff's health and safety in jeopardy.

85. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

86. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and has incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

87. As a direct and proximate result of one or more of the above-stated breach of warranties by Defendant, TPC, Plaintiff, TIMOTHY DIXON, suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against Defendant,

TPC, in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT V
STRICT LIABILITY AGAINST TAKEDA PHARMACEUTICALS USA, INC.

NOW COMES Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of Defendant, TAKEDA PHARMACEUTICALS USA, INC. ("TPUSA") states as follows:

1-71. For paragraphs 1-71 of Count V, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. At all times relevant hereto, TPUSA distributed and/or sold Uloric.

73. At all times relevant hereto, the dangerous propensities of Uloric were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to use the prescribed product and/or medication for their patients.

74. The Uloric product as distributed by Defendants was a defective and unreasonably dangerous product, as Defendants failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for its ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Uloric to lower blood uric acid levels in adults with gout.

75. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician that Defendants' Uloric product was designed and/or manufactured in a way that could cause injuries and damages, including lasting and permanent injuries.

Defendants further failed to inform and/or warn Plaintiff and Plaintiff's treating physician with respect to the selection of appropriate candidates to receive Defendants' Uloric product.

76. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician as to the risks of the Defendants' Uloric product. To the contrary, Defendants withheld information from Plaintiff and Plaintiff's physician regarding the true risks related to ingesting the Uloric product.

77. The warnings that were given by Defendants failed to properly warn the medical community and patients of the increased risk of physical injuries including, but not limited to, dyspnea, acute blood loss, volume overload, acute renal (kidney) failure, and acute gouty flare, resulting in pain and other serious injuries and side effects.

78. The Uloric product, as distributed by Defendants, was dangerous in design at the time it left the Defendants' control.

79. At the time the Uloric product left Defendants' control, there existed feasible and suitable alternative design for the treatment of gout that was capable of preventing Plaintiff's damages.

80. When compared to other feasible alternatives, the Uloric product greatly results in a much higher risk of dyspnea, acute blood loss, volume overload, acute renal (kidney) failure, and acute gouty flare. Other feasible alternative designs exist which do not present the same frequency and severity of risks.

81. At all times relevant to this action, Defendants manufactured, supplied, distributed, and/or sold Uloric in a defective and dangerous condition, as described above, to Plaintiff.

82. Uloric was defective in manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices

and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical manufacturer.

83. The Uloric product prescribed and ingested by Plaintiff was unreasonably dangerous in construction and composition because it deviated in a material way from the Defendants' specifications and performance standards for the product.

84. The dangerous, defective conditions of Uloric were not known, knowable, and / or reasonably visible to Plaintiff and /or Plaintiff's physician or discoverable upon reasonable examination.

85. As a direct, foreseeable and proximate result of Defendants' defective Uloric product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against Defendant, TPUSA, in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT VI
NEGLIGENCE AGAINST TAKEDA PHARMACEUTICALS USA, INC.

NOW COMES Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICALS USA, INC. ("TPUSA"), states as follows:

1-71. For paragraphs 1-71 of Count VI, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein

72. At all times relevant hereto, it was the duty of TPUSA to use reasonable care in the manufacturing, design, distribution, and/or sale of Uloric.

73. In disregard of its aforesaid duty, TPUSA was guilty of one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Uloric without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Uloric while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Uloric;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Uloric was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Uloric was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative hyperuricemia and gout products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Uloric;

g. Advertising, marketing, and recommending the use of Uloric, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Uloric;

h. Representing that Uloric was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative hyperuricemia and gout products were available for use for the purpose for which Uloric was manufactured;

j. Continuing to manufacture and sell Uloric with the knowledge that Uloric was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Uloric so as to avoid the risk of serious harm associated with the use of Uloric;

l. Failing to design and manufacture Uloric so as to ensure the drug was at least as safe and effective as other similar products;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Uloric and that use of Uloric created a high risk of severe injuries;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Uloric.

74. As a direct and proximate result of one or more of the above-stated negligent acts by Defendant, TPUSA, Plaintiff, TIMOTHY DIXON, suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against TPUSA in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT VII
BREACH OF EXPRESS WARRANTY AGAINST TAKEDA PHARMACEUTICALS USA, INC.

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICALS USA, INC. ("TPUSA"), states as follows:

1-71. For paragraphs 1-71 of Count VII, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. Uloric was unreasonably dangerous because it did not conform to express warranties.

73. In the course of business, Defendants designed, manufactured and sold Uloric to be used to lower blood uric acid levels in adults with gout.

74. In selling Uloric to Plaintiff's prescribing physician, the Defendants made representations to the physician about Uloric, affirming that Uloric possessed specific characteristics and would meet a specified level of performance; specifically, that Uloric was appropriate and suitable for the purposes to lower blood uric acid levels in adults with gout.

75. In advertising, marketing and otherwise promoting Defendants' Uloric to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that Uloric was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting Defendants' Uloric, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to prescribe Uloric to their patients.

76. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to Uloric, including, but not limited to, the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that Uloric was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Uloric;

b. Defendants represented to Plaintiff, his physicians and healthcare providers that Uloric was as safe and/or safer than other alternative products then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that Uloric was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff, his physicians and healthcare providers that Uloric was more efficacious than other alternative product, meanwhile concealing information regarding the true efficacy of Uloric.

77. Plaintiff and Plaintiff's physician relied upon Defendants express warranties.

78. Defendants' express warranties induced the Plaintiff's physician to use Uloric to lower blood uric acid levels in Plaintiff, who possessed gout.

79. The Plaintiff's damage was proximately caused because the express warranties made about Uloric were untrue.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against TPUSA in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT VIII
BREACH OF IMPLIED WARRANTIES AGAINST TAKEDA PHARMACEUTICALS USA, INC.

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICALS USA, INC. ("TPUSA"), states as follows:

1-71. For paragraphs 1-71 of Count VIII, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. Uloric was unreasonably dangerous because it did not conform to implied warranties.

73. At all relevant and material times, Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and otherwise placed into the stream of commerce Uloric.

74. Defendants impliedly warranted that Uloric was merchantable and was fit for the ordinary purposes for which it was intended.

75. Defendants impliedly warranted that their Product was of merchantable quality, safe and fit for the intended use to lower blood uric acid levels in adults with gout and that it was properly and adequately tested prior to being placed in the stream of commerce.

76. When Uloric was prescribed to the Plaintiff, it was being used for the ordinary purposes for which it was intended.

77. Defendants intended that Uloric be prescribed and taken by Plaintiff for the purposes and in the manner that Plaintiff's physician prescribed it, in accordance with the product specifications provided by Defendants.

78. Defendants were aware that consumers, such as the Plaintiff, would be prescribed with Uloric by their treating physicians in accordance with the product specifications provided by Defendants.

79. Plaintiff was a foreseeable user of Defendants' Uloric and was in privity with Defendants.

80. Defendants breached implied warranties with respect to Uloric, including, but not limited to the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Uloric was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Defendants' Uloric;

b. Defendants represented to Plaintiff, Plaintiff's physicians and healthcare providers that the Defendants' Uloric was safe, as safe as and/or safer than other alternative medications, meanwhile Defendants fraudulently concealed information, which demonstrated that Uloric was not safe, as safe as or safer than alternatives and other products available on the market; and

c. Defendants represented to Plaintiff, Plaintiff's physicians and healthcare providers that the Defendants' Uloric was more efficacious than other alternative products and/or medications, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Defendants' Uloric.

81. The Plaintiff individually and/or by and through his physician, relied upon Defendants' implied warranties in consenting to be prescribed and to have ingested Uloric.

82. In reliance upon Defendants' implied warranties, Plaintiff's prescribing physician used Defendants' Uloric to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

83. Defendants breached their implied warranties to Plaintiff because Defendants' Uloric was not of merchantable quality, safe and fit for its intended use, as warranted, nor was it adequately tested prior to being placed in the stream of commerce.

84. Defendants' breach of their implied warranties consuming Defendants' unreasonably dangerous and defective product and placing said Plaintiff's health and safety in jeopardy.

85. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

86. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained severe and permanent injuries requiring past and future medical treatment, and resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and has incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

87. As a direct and proximate result of one or more of the above-stated breach of warranties by Defendant, TPUSA, Plaintiff, TIMOTHY DIXON, suffered grievous bodily

injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against TPUSA in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT IX
STRICT LIABILITY AGAINST TAKEDA PHARMACEUTICALS AMERICA, INC.

NOW COMES Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of Defendant, TAKEDA PHARMACEUTICALS AMERICA, INC. ("TPA") states as follows:

1-71. For paragraphs 1-71 of Count IX, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. At all times relevant hereto, TPA distributed and/or sold Uloric.

73. At all times relevant hereto, the dangerous propensities of Uloric were known to Defendants, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold their respective products, and not known to ordinary physicians who would be expected to use the prescribed product and/or medication for their patients.

74. The Uloric product as distributed by Defendants was a defective and unreasonably dangerous product, as Defendants failed to provide appropriate and adequate warnings and instructions to render the products reasonably safe for its ordinary, intended, and reasonably foreseeable uses; in particular – the common, foreseeable and intended use of Uloric to lower blood uric acid levels in adults with gout.

75. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician that Defendants' Uloric product was designed and/or manufactured in a way that could cause injuries and damages, including lasting and permanent injuries. Defendants further failed to inform and/or warn Plaintiff and Plaintiff's treating physician with respect to the selection of appropriate candidates to receive Defendants' Uloric product.

76. Defendants failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician as to the risks of the Defendants' Uloric product. To the contrary, Defendants withheld information from Plaintiff and Plaintiff's physician regarding the true risks related to ingesting the Uloric product.

77. The warnings that were given by Defendants failed to properly warn the medical community and patients of the increased risk of physical injuries including, but not limited to, dyspnea, acute blood loss, volume overload, acute renal (kidney) failure, and acute gouty flare, resulting in pain and other serious injuries and side effects.

78. The Uloric product, as distributed by Defendants, was dangerous in design at the time it left the Defendants' control.

79. At the time the Uloric product left Defendants' control, there existed feasible and suitable alternative design for the treatment of gout that was capable of preventing Plaintiff's damages.

80. When compared to other feasible alternatives, the Uloric product greatly results in a much higher risk of dyspnea, acute blood loss, volume overload, acute renal (kidney) failure, and acute gouty flare. Other feasible alternative designs exist which do not present the same frequency and severity of risks.

81. At all times relevant to this action, Defendants manufactured, supplied, distributed, and/or sold Uloric in a defective and dangerous condition, as described above, to Plaintiff.

82. Uloric was defective in manufacture and construction when it left the hands of Defendants in that its manufacture and construction deviated from good manufacturing practices and/or manufacturing specifications as would be used and/or maintained by a reasonably prudent and careful medical manufacturer.

83. The Uloric product prescribed and ingested by Plaintiff was unreasonably dangerous in construction and composition because it deviated in a material way from the Defendants' specifications and performance standards for the product.

84. The dangerous, defective conditions of Uloric were not known, knowable, and / or reasonably visible to Plaintiff and /or Plaintiff's physician or discoverable upon reasonable examination.

85. As a direct, foreseeable and proximate result of Defendants' defective Uloric product, Plaintiff suffered grievous bodily injuries and consequent economic and other losses, as referenced above, when his physicians, lacking adequate warnings and other appropriate facts that were misrepresented or omitted from the information (if any) Defendants provided to physicians for their respective products. Plaintiff has suffered and will continue to suffer injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against Defendant, TPA, in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT X
NEGLIGENCE AGAINST TAKEDA PHARMACEUTICALS AMERICA, INC.

NOW COMES Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and

complaining of TAKEDA PHARMACEUTICALS AMERICA, INC. ("TPA"), states as follows:

1-71. For paragraphs 1-71 of Count X, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein

72. At all times relevant hereto, it was the duty of TPA to use reasonable care in the manufacturing, design, distribution, and/or sale of Uloric.

73. In disregard of its aforesaid duty, TPA was guilty of one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Uloric without thorough and adequate pre and post-market testing of the product;

b. Manufacturing, producing, promoting, advertising, formulating, creating, developing, and designing, and distributing Uloric while negligently and intentionally concealing and failing to disclose clinical data which demonstrated the risk of serious harm associated with the use of Uloric;

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Uloric was safe for its intended use;

d. Failing to disclose and warn of the product defect to the regulatory agencies, the medical community, and consumers that Defendants knew and had reason to know that Uloric was indeed unreasonably unsafe and unfit for use by reason of the product's defect and risk of harm to its users;

e. Failing to warn Plaintiff, the medical and healthcare community, and consumers that the product's risk of harm was unreasonable and that there were safer and effective alternative hyperuricemia and gout products available to Plaintiff and other consumers;

f. Failing to provide adequate instructions, guidelines, and safety precautions to those persons to whom it was reasonably foreseeable would use Uloric;

g. Advertising, marketing, and recommending the use of Uloric, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with, and inherent in, the use of Uloric;

h. Representing that Uloric was safe for its intended use when in fact Defendants knew and should have known the product was not safe for its intended purpose;

i. Failing to disclose to and inform the medical community and consumers that other forms of safer and effective alternative hyperuricemia and gout products were available for use for the purpose for which Uloric was manufactured;

j. Continuing to manufacture and sell Uloric with the knowledge that Uloric was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Uloric so as to avoid the risk of serious harm associated with the use of Uloric;

l. Failing to design and manufacture Uloric so as to ensure the drug was at least as safe and effective as other similar products;

m. Failing to ensure the product was accompanied by proper and accurate warnings about possible adverse side effects associated with the use of Uloric and that use of Uloric created a high risk of severe injuries;

n. Failing to conduct adequate testing, including pre-clinical and clinical testing, and post-marketing surveillance to determine the safety of Uloric.

74. As a direct and proximate result of one or more of the above-stated negligent acts by Defendant, TPA, Plaintiff, TIMOTHY DIXON, suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against TPA in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT XI
BREACH OF EXPRESS WARRANTY AGAINST TAKEDA PHARMACEUTICALS AMERICA, INC.

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICALS AMERICA, INC. ("TPA"), states as follows:

1-71. For paragraphs 1-71 of Count VII, Plaintiff restates and re-alleges paragraphs 1-71

in the foregoing paragraphs as though fully set forth herein.

72. Uloric was unreasonably dangerous because it did not conform to express warranties.

73. In the course of business, Defendants designed, manufactured and sold Uloric to be used to lower blood uric acid levels in adults with gout.

74. In selling Uloric to Plaintiff's prescribing physician, the Defendants made representations to the physician about Uloric, affirming that Uloric possessed specific characteristics and would meet a specified level of performance; specifically, that Uloric was appropriate and suitable for the purposes to lower blood uric acid levels in adults with gout.

75. In advertising, marketing and otherwise promoting Defendants' Uloric to physicians, hospitals and other healthcare providers, Defendants' expressly warranted that Uloric was safe for use and reasonably fit for their intended purposes. In advertising, marketing and otherwise promoting Defendants' Uloric, Defendants intended that physicians, hospitals and other healthcare providers rely upon their representations regarding safety and fitness in an effort to induce them to prescribe Uloric to their patients.

76. Defendants breached express representations and warranties made to the Plaintiff, as well as Plaintiff's physicians and healthcare providers, with respect to Uloric, including, but not limited to, the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions among other ways that Uloric was safe, meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Uloric;

b. Defendants represented to Plaintiff, his physicians and healthcare providers that Uloric was as safe and/or safer than other alternative products then on the market, meanwhile Defendants fraudulently concealed information that demonstrated that

Uloric was not safer than alternative therapies and products available on the market; and

c. Defendants represented to Plaintiff, his physicians and healthcare providers that Uloric was more efficacious than other alternative product, meanwhile concealing information regarding the true efficacy of Uloric.

77. Plaintiff and Plaintiff's physician relied upon Defendants express warranties.

78. Defendants' express warranties induced the Plaintiff's physician to use Uloric to lower blood uric acid levels in Plaintiff, who possessed gout.

79. The Plaintiff's damage was proximately caused because the express warranties made about Uloric were untrue.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against TPA in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

COUNT XIII
BREACH OF IMPLIED WARRANTIES AGAINST TAKEDA PHARMACEUTICALS AMERICA, INC.

NOW COMES the Plaintiff, TIMOTHY DIXON, by and through undersigned counsel, and complaining of TAKEDA PHARMACEUTICALS AMERICA, INC. ("TPA"), states as follows:

1-71. For paragraphs 1-71 of Count XIII, Plaintiff restates and re-alleges paragraphs 1-71 in the foregoing paragraphs as though fully set forth herein.

72. Uloric was unreasonably dangerous because it did not conform to implied warranties.

73. At all relevant and material times, Defendants designed, manufactured, labeled, supplied, sold, distributed, marketed and otherwise placed into the stream of commerce Uloric.

74. Defendants impliedly warranted that Uloric was merchantable and was fit for the ordinary purposes for which it was intended.

75. Defendants impliedly warranted that their Product was of merchantable quality, safe and fit for the intended use to lower blood uric acid levels in adults with gout and that it was properly and adequately tested prior to being placed in the stream of commerce.

76. When Uloric was prescribed to the Plaintiff, it was being used for the ordinary purposes for which it was intended.

77. Defendants intended that Uloric be prescribed and taken by Plaintiff for the purposes and in the manner that Plaintiff's physician prescribed it, in accordance with the product specifications provided by Defendants.

78. Defendants were aware that consumers, such as the Plaintiff, would be prescribed with Uloric by their treating physicians in accordance with the product specifications provided by Defendants.

79. Plaintiff was a foreseeable user of Defendants' Uloric and was in privity with Defendants.

80. Defendants breached implied warranties with respect to Uloric, including, but not limited to the following particulars:

a. Defendants represented to Plaintiff and Plaintiff's physicians and healthcare providers through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the Defendants' Uloric was of merchantable quality and safe when used for its intended purpose meanwhile Defendants fraudulently withheld and concealed information about the substantial risks of serious injury associated with using Defendants' Uloric;

b. Defendants represented to Plaintiff, Plaintiff's physicians and healthcare providers that the Defendants' Uloric was safe, as safe as and/or safer than other alternative medications, meanwhile Defendants fraudulently concealed information, which

demonstrated that Uloric was not safe, as safe as or safer than alternatives and other products available on the market; and

c. Defendants represented to Plaintiff, Plaintiff's physicians and healthcare providers that the Defendants' Uloric was more efficacious than other alternative products and/or medications, meanwhile Defendants fraudulently concealed information, regarding the true efficacy of Defendants' Uloric.

81. The Plaintiff individually and/or by and through his physician, relied upon Defendants' implied warranties in consenting to be prescribed and to have ingested Uloric.

82. In reliance upon Defendants' implied warranties, Plaintiff's prescribing physician used Defendants' Uloric to treat Plaintiff in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants and in accordance with the instructions for use and product specification provided by Defendants.

83. Defendants breached their implied warranties to Plaintiff because Defendants' Uloric was not of merchantable quality, safe and fit for its intended use, as warranted, nor was it adequately tested prior to being placed in the stream of commerce.

84. Defendants' breach of their implied warranties consuming Defendants' unreasonably dangerous and defective product and placing said Plaintiff's health and safety in jeopardy.

85. Defendants' acts were motivated by financial gain while the adverse consequences of the conduct were actually known by Defendants. Defendants' conduct was outrageous, fraudulent, oppressive, done with malice and with gross negligence, and evidenced reckless disregard and indifference to Plaintiff's rights, health and safety.

86. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, Plaintiff has experienced significant mental and physical pain and suffering, has sustained severe and permanent injuries requiring past and future medical treatment, and

resulting in disability, impairment, loss of enjoyment of life, loss of care, comfort, and has incurred financial or economic loss, including, but not limited to, obligations for medical expenses, lost income, and other damages.

87. As a direct and proximate result of one or more of the above-stated breach of warranties by Defendant, TPA, Plaintiff, TIMOTHY DIXON, suffered grievous bodily injuries and consequent economic and other losses, including pain and suffering, loss of a normal life, medical expenses, lost income and disability.

WHEREFORE, Plaintiff, TIMOTHY DIXON, prays for judgment against TPA in such an amount in excess of this Court's jurisdictional requisite as will fairly and adequately compensate for the losses herein alleged.

Respectfully submitted,

BY: */s/ Lisa Causey-Streete*
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ATTORNEYS FOR PLAINTIFF

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

TIMOTHY DIXON,	)	
	)	
Plaintiff,	)	
	)	Case No. 1:20-cv-2325
vs.	)	
	)	**JURY TRIAL DEMANDED**
TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS U.S.A., INC., and TAKEDA PHARMACEUTICALS AMERICA, INC.;	)	
	)	
Defendants.		

DEMAND FOR JURY TRIAL

Plaintiff, by and through his undersigned counsel, hereby demands a trial by jury as to all issues and claims asserted in this Complaint.

/s/ Lisa Causey-Streete
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Attorneys for Plaintiff

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was electronically filed through the Court's CM/ECF system on April 15, 2020, which shall send notification of such filing to all CM/ECF participants.

/s/ Lisa Causey-Streete
Lisa Causey-Streete