UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOHNEEN S. SPICE,	)	
	)	**CIVIL ACTION NO.**
PLAINTIFF,	)	
v.	)	
JANSSEN PHARMACEUTICALS, INC.,	)	**COMPLAINT**
DEFENDANT.	)	

COMES NOW PLAINTIFF, Johneen S. Spice ("Plaintiff"), and by and for her Complaint against Defendant, states and alleges upon information and belief and based upon the investigation of counsel, as follows:

INTRODUCTION

This is a personal injury action for damages arising from Plaintiff's use of Defendant Janssen Pharmaceuticals, Inc.'s dangerously defective prescription drug, Elmiron (pentosyn polysulfate sodium), prescribed for the treatment of interstitial cystitis and bladder pain. Defendant designed, marketed, and distributed Elmiron in the United States, all the while knowing significant risks that were never disclosed to the medical and healthcare community, including Plaintiff's prescribing doctor, Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff, and/or the public in general. Further, Defendant failed to provide adequate warnings to patients and the medical community, including Plaintiff's prescribing physician, of the risks associated with using the drug.

Throughout the time Defendant marketed Elmiron, Defendant withheld material adverse events from the public, medical community and FDA. Defendant failed to disclose the serious link between Elmiron use and significant visual damage, including pigmentary maculopathy. Ultimately, tens of thousands of patients, including Plaintiff, were placed at risk and harmed as a result of this misleading conduct.

PARTIES

1. At all times relevant hereto, Plaintiff Johneen S. Spice is and was a citizen and resident of Mishawaka, St. Joseph County, Indiana.

2. Upon information and belief, Plaintiff consumed and regularly used Defendant's Elmiron (pentosyn polysulfate sodium) product. As a result of her use of Defendant's Elmiron product, Plaintiff suffered from severe physical and emotional injuries, including but not limited to loss of vision, including a diagnosis of macular degeneration. Based on information and belief, Plaintiff's ingestion of Elmiron caused her injuries.

3. Defendant Janssen Pharmaceuticals, Inc, is a Pennsylvania corporation with a principal place of business located at 800 Ridgeview Drive, Horsham, Pennsylvania 19044.

4. Defendant directly or through their agents or employees designed, manufactured, marketed, and sold Elmiron in the United States, which is used to manage symptoms of interstitial cystitis and painful bladder syndrome.

JURISDICTION AND VENUE

5. This Court has diversity jurisdiction over this action pursuant to 28 U.S.C. §1332, because the amount in controversy exceeds $75,000.00 and the Parties are citizens of different states.

6. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. §1367.

7. Venue is proper in this Court pursuant to 28 U.S.C. §1391 because Defendant Janssen Pharmaceuticals is a Pennsylvania Corporation.

8. Defendant currently transacts business in within this District by selling its products within this District and throughout the United States.

GENERAL ALLEGATIONS

A. Interstitial Cystitis

9. Interstitial cystitis is a medical condition in the bladder that causes bladder pressure, bladder pain, and sometimes pelvic pain. There is no known cause of interstitial cystitis. The symptoms can range from mild to debilitating. The disease is known to affect women more often than men. There is no known cure for interstitial cystitis or painful bladder syndrome.

10. The American Urological Association has established guidelines to provide a clinical framework for the diagnosis and treatment of interstitial cystitis. These guidelines were created by a comprehensive review of the literature. The guidelines include principles for the diagnosis of interstitial cystitis. The AUA guidelines further state that initial treatment type and level should depend on

symptom severity, clinician judgment, and patient preferences. Treatments that may be offered are divided into first-, second-, third-, fourth-, fifth-, and sixth-line groups based on the balance between potential benefits to the patient, potential severity of adverse events ("AEs") and the reversibility of the treatment. Second-line treatment of interstitial cystitis includes multi-modal pain management approaches including manual therapy and pharmacological options including amitriptyline, cimetidine, hydroxyzine, or pentosyn polysulfate.

B. Elmiron

11. Elmiron (pentosyn polysulfate sodium) was approved in 1996 to be used as a treatment for interstitial cystitis and painful bladder symptoms.

12. Upon information and belief, Elmiron was granted an Orphan Drug designation in 1995. The original NDA was submitted in 1991, which was deemed non-approvable in 1993. A second non-approvable letter was sent in 1994 over concerns about the lack of data on efficacy of the drug. Elmiron was originally submitted to by Baker Norton Pharmaceuticals, a division of Ivax Pharmaceuticals that has since been purchased by Teva Pharmaceuticals, Inc.

13. Elmiron (Pentosan polysulfate sodium) is a low molecular weight heparin-like compound. It has anticoagulant and fibrinolytic effects, but the mechanism of action of pentosan polysulfate sodium in interstitial cystitis is not known.

14. Upon information and belief, Elmiron was first approved by FDA in September 1996 for painful bladder symptoms at which time Baker Norton Pharmaceuticals was the sponsor of the New Drug Application.

15. Upon information and belief, in 1997 Elmiron was purchased from Baker Norton Pharmaceuticals and Ivax by Alza Pharmaceuticals.

16. Upon information and belief, in 2002, Alza Corporation was acquired by Ortho-McNeil Pharmaceuticals, Inc, a subsidiary of Janssen Pharmaceuticals. Janssen Pharmaceuticals has been the sponsor of the NDA since that time.

17. The label and prescribing information that accompany Elmiron when prescribed to patients contains the following: "Warnings: None."

18. According to the Drugs@FDA website, the label for Elmiron has been updated on approximately five occasions, at no time has it contained any information about vision loss, including pigmentary maculopathy, in any section of the label. The only mention in the label of any visual adverse events is a disclosure in the Adverse Reactions section that reveals clinical trial patients reported conjunctivitis, optic neuritis, amblyopia, and retinal hemorrhage. However, none of these adverse events are related to pigmentary maculopathy.

19. Elmiron is known to take long time to exert an effect and patients who are prescribed Elmiron are advised to take the drug for at least six months in order to determine if there is an effect. For those patients who take the drug, the drug is known to be used for long-term use and in many patients, use is expected to last years, if not decades.

C. Drug-Induced Retinal Toxicity

20. The administration of drugs that are physiologically foreign to the body can lead to adverse side effects or toxicity with significant consequences. The retina is especially susceptible to the effects of systemic drugs. It has an extensive dual blood supply from the retina and is one of the most metabolically active tissues in the body. The retina has minimal ability to regenerate and is therefore at high risk of drug toxicity. Thus, it is critical that eye care professionals are aware and monitor for adverse drug effects, especially those affecting the retina.

21. For example, the anti-malarial drug Plaquenil (hydroxychloroquine) is known to be associated with retinal toxicity. The label that accompanies that drug contains explicit instructions of the risk of injury and monitoring for signs of toxicity.

> Irreversible retinal damage has been observed in some patients who had received hydroxychloroquine sulfate. Significant risk factors for retinal damage include daily doses of hydroxychloroquine sulfate greater than 6.5 mg/kg (5 mg/kg base) of actual body weight, durations of use greater than five years, subnormal glomerular filtration, use of some concomitant drug products such as tamoxifen citrate and concurrent macular disease.
>
> A baseline ocular examination is recommended within the first year of starting PLAQUENIL. The baseline exam should include: best corrected distance visual acuity (BCVA), an automated threshold visual field (VF) of the central 10 degrees (with retesting if an abnormality is noted), and spectral domain ocular coherence tomography (SD-OCT).
>
> For individuals with significant risk factors (daily dose of hydroxychloroquine sulfate greater than 5.0 mg/kg base of actual body weight, subnormal glomerular filtration, use of tamoxifen citrate or concurrent macular disease) monitoring should include annual examinations which include BCVA, VF and SD-OCT. For individuals without significant risk factors, annual exams can usually be deferred until five years of treatment.

> In individuals of Asian descent, retinal toxicity may first be noticed outside the macula. In patients of Asian descent, it is recommended that visual field testing be performed in the central 24 degrees instead of the central 10 degrees.
>
> It is recommended that hydroxychloroquine be discontinued if ocular toxicity is suspected and the patient should be closely observed given that retinal changes (and visual disturbances) may progress even after cessation of therapy.

D. Elmiron-Induced Macular Toxicity

22. In November 2018, *Pearce, et al*, reported a case series of patients known to be long term users of Elmiron that presented with an atypical maculopathy that resulted in significant vision loss.

23. A follow-up study by the same authors (*Hanif, et al.*) included a retrospective review of 219 patients seen at Emory and evaluated vision loss as additional support for the association between Elmiron use and vision loss.

24. In *Jain et al.,* the authors reported a large, administrative, U.S. database was used to examine the association of PPS use and a diagnosis of a macular disorder. Their exposure cohort (PPS users) was matched 1:5 with an unexposed cohort of patients (not necessarily IC/BPS patients). The primary outcome was any new diagnosis of a hereditary or secondary pigmentary retinopathy or any new diagnosis of dry age-related macular degeneration (AMD) or drusen in addition to the previously described retinopathy. At seven years, there was a statistically significant increase in the exposed group in multivariate analysis (odds ratio [OR] 1.41; 95% confidence interval [CI] 1.09–1.83; p=0.009].

25. At a recent meeting of the American Academy of Ophthalmologists in San Francisco, Vora et al., presented their findings using data from Kaiser Permanente and identified 140 patients (from the database of 4.3 million) who had taken an average of 5000 pills over a 15-year period. Of the 140 exposed patients, 91 agreed to an examination and of those, 22 patients showed clear evidence of this specific maculopathy, which authors believe was associated with PPS exposure. This work has since been published in the journal, *Opthamology* in January 2020. According to Dr. Vora,

> You have a patient with a chronic condition like interstitial cystitis, for which there is no cure and no effective treatment. They get put on these medications because it's thought to have few side effects and few risks, and no one thinks about it again. And year after year, the number of pills they're taking goes up and up.

Because it's unclear how much medication is too much, Dr. Vora is reported to recommend patients who show no signs of toxicity be screened for retina damage at least once a year. For those who do show some signs of damage, he recommends they speak with their urologist or OB/GYN about discontinuing the medication.

26. *Greenlee et al.* postulated that the mechanism of toxicity of pentosyn polysulfate may relate to the antagonist properties of pentosyn polysulfate towards the fibroblast growth factors 1, 2, and 4. The authors of that publication reported that several known FGF antagonists are associated with significant ocular side effects.

27. In *Lyons, et al.*, published in *Obstetrics and Gynecology* in 2020, the authors made the following screening and follow-up recommendations:

a. Providers discuss the risks associated with pentosan polysulfate with their patients and prescribe the lowest necessary dose and duration of

pentosan polysulfate for patients who require long-term treatment. Providers may discuss alternative treatments for interstitial cystitis at their discretion.

b. A baseline examination with fundus photography, optical coherence tomography, and fundus autofluorescence imaging.
c. Testing is repeated within 5 years after pentosan polysulfate initiation and annually, thereafter. Some patients may be at higher risk for developing pentosan polysulfate maculopathy and may benefit from either more frequent screening examinations or drug avoidance.
d. We recommend that patients diagnosed with pentosan polysulfate maculopathy stop taking the drug and discuss alternative interstitial cystitis management options with their treating physician.

28. Since the original report, there have been more than a dozen papers published in the medical literature regarding the atypical maculopathy associated with Elmiron use. Despite these publications, Defendant has made no change to the label in the United States or taken any steps to warn the medical community and users of the drug regarding these effects.

29. More troubling, Defendant made label changes in other countries to warn users of these injuries. For example, in September 2019, Defendant changed the label of Elmiron in Canada to reflect the following warning:

> **Ophthalmologic**
> Post-market cases of pigmentary maculopathy have been reported with chronic use of pentosan polysulfate sodium (PPS). Visual symptoms in these cases included difficulty reading and prolonged dark adaptation. All patients should have regular ophthalmic examinations for early detection of pigmentary maculopathy, particularly those with long-term use of PPS. If pigmentary maculopathy is confirmed, treatment discontinuation should be considered.

E. Elmiron U.S. Label Change

30. From when Elmiron was first sold in the United States until June 16, 2020, Defendant's U.S. Elmiron did not warn U.S. healthcare professionals and/or

consumers of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

31. From when Elmiron was first sold in the United States until June 16, 2020, upon information and belief, Defendant did not attempt to warn U.S. healthcare professionals and/or consumers of the risk of serious visual complications, including, but not limited to, pigmentary maculopathy associated with long-term Elmiron use.

32. Upon information and belief, beginning on June 16, 2020, Defendant's Elmiron label contained the following language as to the risk of serious, vision-related complications:

> **WARNINGS**
> **Retinal Pigmentary Changes**
>
> Pigmentary changes in the retina, reported in the literature as pigmentary maculopathy, have been identified with long-term use of ELMIRON® (see ADVERSE REACTIONS). Although most of these cases occurred after 3 years of use or longer, cases have been seen with a shorter duration of use. While the etiology is unclear, cumulative dose appears to be a risk factor.
>
> Visual symptoms in the reported cases included difficulty reading, slow adjustment to low or reduced light environments, and blurred vision. The visual consequences of these pigmentary changes are not fully characterized. Caution should be used in patients with retinal pigment changes from other causes in which examination findings may confound the appropriate diagnosis, follow-up, and treatment. Detailed ophthalmologic history should be obtained in all patients prior to starting treatment with ELMIRON®. If there is a family history of hereditary pattern dystrophy, genetic testing should be considered. For patients with pre-existing ophthalmologic conditions, a comprehensive baseline retinal examination (including color fundoscopic photography, ocular coherence tomography (OCT), and auto-fluorescence imaging) is recommended prior to starting therapy. A baseline retinal examination (including OCT and auto-fluorescence imaging) is suggested for all patients within six months of initiating treatment and periodically while

> continuing treatment. If pigmentary changes in the retina develop, then risks and benefits of continuing treatment should be re-evaluated, since these changes may be irreversible. Follow-up retinal examinations should be continued given that retinal and vision changes may progress even after cessation of treatment.

PLAINTIFF SPECIFIC FACTS

33. Upon information and belief, in or about 2011, Plaintiff's treating medical physician prescribed Elmiron to Plaintiff due to Plaintiff's medically diagnosed painful bladder and/or interstitial cystitis. Defendant represented Elmiron to be an appropriate and suitable product for such purposes.

34. In or about 2017, Plaintiff began to experience visual symptoms, and was subsequently diagnosed with permanent retinal injury and vision loss associated with Elmiron use in July of 2017.

35. As a result of Defendant's actions and inactions, Plaintiff was injured due to Elmiron which caused Plaintiff various injuries and damages due to her vision loss. Plaintiff accordingly seeks damages associated with these injuries.

36. Defendant ignored reports from patients and health care providers throughout the United States of Elmiron's failure to perform as intended and injuries associated with long-term use, 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 Elmiron's design as the cause of the injuries, Defendant continued to market Elmiron as a safe and effective prescription drug for interstitial cystitis.

37. Defendant did not timely or adequately apprise the public and physicians, including Plaintiff's physicians, of the adverse effect or defects in Elmiron despite Defendant's knowledge that it was associated with visual effects following use. Defendant did not timely or adequately apprise the public and physicians, including Plaintiff's physicians, to monitor Elmiron users' vision and eyes with regular examination.

38. Defendant's Elmiron was at all times utilized and prescribed in a manner foreseeable to Defendant, as Defendant generated the instructions for use for Plaintiff to take Elmiron.

39. Plaintiff and Plaintiff's physicians foreseeably used the Defendant's Elmiron, and did not misuse or alter the Elmiron in an unforeseeable manner.

40. Through their affirmative misrepresentations and omissions, Defendant actively concealed from Plaintiff and his/her physicians the true and significant risks associated with Elmiron consumption.

41. As a result of Defendant's actions, Plaintiff and her 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 Defendant's conduct.

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

43. Plaintiff, as a direct and proximate result of Elmiron usage, suffered severe mental and physical pain and suffering and has sustained permanent injuries

and emotional distress, along with economic loss due to medical expenses and living-related expenses due to her new lifestyle.

44. Plaintiff's physicians would not have prescribed Elmiron had Defendant properly disclosed the risks associated with its use or, in the alternative, would have actively monitored her vision with regular eye exams.

EQUITABLE TOLLING OF STATUTE OF LIMITATIONS

45. Defendant failed to disclose a known defect and affirmatively misrepresented that Elmiron was safe for its intended use. Further, Defendant actively concealed the true risks associated with the use of Elmiron. Neither Plaintiff nor the prescribing physicians had knowledge that Defendant was engaged in the wrongdoing alleged herein.

46. Because of Defendant's concealment of and misrepresentations regarding the true risks associated with Elmiron, Plaintiff could not have reasonably discovered Defendant's wrongdoing at any time prior to the commencement of this action.

47. Thus, because Defendant fraudulently concealed the defective nature of Elmiron and the risks associated with its use, the running of any statute of limitations has been tolled. Likewise, Defendant is estopped from relying on any statute of limitations.

48. Additionally, and alternatively, Plaintiff files this lawsuit within the applicable limitations period of first suspecting that Elmiron caused the appreciable harm sustained by Plaintiff. Plaintiff did not have actual or constructive knowledge

of acts 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

49. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

50. At all times relevant hereto, Defendant manufactured, designed, distributed, and/or sold Elmiron.

51. At all times relevant hereto, the dangerous propensities of Elmiron were known to Defendant, or reasonably and scientifically knowable to them, through appropriate research and testing by known methods, at the time it distributed, supplied, or sold its product, and not known to ordinary physicians who would be expected to prescribe the drug to their patients.

52. The Elmiron product as distributed by Defendant was a defective and unreasonably dangerous product, as Defendant 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 Elmiron to treat painful bladder syndrome and interstitial cystitis.

53. Defendant failed to properly and adequately warn and instruct Plaintiff and Plaintiff's treating physician that Defendant's Elmiron product was designed

and/or manufactured in a way that could cause injuries and damages, including lasting and permanent visual injuries.

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

55. The Elmiron product, as distributed by Defendant, was dangerous in design at the time it left the Defendant's control.

56. Plaintiff did not misuse or materially alter Elmiron as prescribed and dispensed to Plaintiff and used by Plaintiff.

57. At the time the Elmiron product left Defendant's control, there existed feasible and suitable alternative design for the treatment of interstitial cystitis that was capable of preventing Plaintiff's damages or alternatively a plan for monitoring ocular health in association with use of Elmiron.

58. When compared to other feasible alternatives, the Elmiron product greatly results in a much higher risk of visual injuries and side effects. Other feasible alternative treatments exist which do not present the same frequency and severity of risks.

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

60. The Elmiron received by Plaintiff did not perform safely as an ordinary

consumer would have expected it to perform when used in a reasonably foreseeable way.

61. Furthermore, a reasonable patient would conclude the possibility and seriousness of harm outweighs the benefit from its normal, intended use.

62. As a direct, foreseeable and proximate result of Defendant's defective Elmiron 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) Defendant provided to physicians for its product. Plaintiff has suffered injury of a personal and pecuniary nature, including pain and suffering, medical expenses, lost income and disability.

COUNT II
NEGLIGENCE

63. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

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

65. Defendant failed to exercise ordinary care in the manufacture, sale, labeling, and marketing of Elmiron in that Defendant knew or should have known that Elmiron created a high risk of unreasonable harm to Plaintiff and other users.

66. In disregard of its duty, Defendant committed one or more of the following negligent acts or omissions:

a. Manufacturing, producing, promoting, formulating, creating,

developing, designing, selling, and distributing Elmiron without thorough and adequate pre- and post-market testing of the product;

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

c. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Elmiron 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 Defendant knew and had reason to know that Elmiron 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 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 Elmiron;

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

h. Representing that Elmiron was safe for its intended use when in fact Defendant 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 products were available for use for the purpose for which Elmiron was manufactured;

j. Continuing to manufacture and sell Elmiron with the knowledge

that Elmiron was unreasonably unsafe and dangerous;

k. Failing to use reasonable and prudent care in the design, research, manufacture, and development of Elmiron so as to avoid the risk of serious harm associated with the use of Elmiron. Failing to design and manufacture Elmiron so as to ensure the drug was at least as safe and effective as other similar products;

l. Failing to ensure the product was accompanied by proper and accurate warnings about requiring baseline visual examinations and regular eye examinations while using the drug to monitor for retinal or macular toxicity associated with the use of Elmiron;

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

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

67. As a direct and proximate result of one or more of the above-stated negligent acts by Defendant, Plaintiff 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.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein, and prays judgment in her favor and against the Defendant awarding the following:

1. A monetary award, sufficient to compensate Plaintiff for the following categories of damages:

a. General damages for severe physical pain, mental suffering, inconvenience, and loss of the enjoyment of life;

b. Past, present, and future damages for costs of medical and rehabilitative treatment and care for Plaintiff;

c. Past wage loss and future loss of earning capacity.

2. Plaintiff's cost of this action, together with interest on past and future special and general damage amounts from the date of injury at the legal rate until paid, interest on any judgment awarded herein at the legal rate until paid, and such other and further relief as the Court deems equitable and just.

3. Any other award this Court deems equitable and just.

4. Plaintiff demands a jury trial.

Date: July 8, 2020

SIMMONS HANLY CONROY, LLC

/s/ Trent B. Miracle

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