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8 UNITED STATES DISTRICT COURT  
9 NORTHERN DISTRICT OF CALIFORNIA

10 \_\_\_\_\_, Individually and on Behalf  
11 of All Others Similarly Situated,

12 Plaintiff,

13 v.

14  
15 ACELRX PHARMACEUTICALS, INC.,  
16 VINCENT J. ANGOTTI, and RAFFI  
ASADORIAN,

17 Defendants.  
18

Case No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE  
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

19 Plaintiff, individually and on behalf of all others similarly situated, by Plaintiff's  
20 undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based  
21 upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and  
22 belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through  
23 Plaintiff's attorneys, which included, among other things, a review of the Defendants'  
24 public documents, conference calls and announcements made by Defendants, United States  
25 ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases  
26 published by and regarding AcelRx Pharmaceuticals, Inc. ("AcelRx" or the "Company"),  
27 analysts'  
28

1 reports and advisories about the Company, and information readily obtainable on the Internet.  
2 Plaintiff believes that substantial additional evidentiary support will exist for the allegations set  
3 forth herein after a reasonable opportunity for discovery.

4 **NATURE OF THE ACTION**

5 1. This is a federal securities class action on behalf of a class consisting of all persons  
6 and entities other than Defendants that purchased or otherwise acquired AcelRx securities between  
7 March 17, 2020 and February 12, 2021, both dates inclusive (the “Class Period”), seeking to  
8 recover damages caused by Defendants’ violations of the federal securities laws and to pursue  
9 remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange  
10 Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.  
11

12 2. AcelRx is a specialty pharmaceutical company that focuses on the development and  
13 commercialization of therapies for the treatment of acute pain. The Company’s lead product  
14 candidate is DSUVIA, a 30 mcg sufentanil sublingual tablet for the treatment of moderate-to-  
15 severe acute pain.  
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17 3. On November 2, 2018, AcelRx announced that the U.S. Food and Drug  
18 Administration (“FDA”) had approved DSUVIA for the management of acute pain in adults that  
19 is severe enough to require an opioid analgesic in certified medically supervised healthcare  
20 settings, such as hospitals, surgical centers, and emergency departments.  
21

22 4. Throughout the Class Period, Defendants made materially false and misleading  
23 statements regarding the Company’s business, operations, and compliance policies. Specifically,  
24 Defendants made false and/or misleading statements and/or failed to disclose that: (i) AcelRx had  
25 deficient disclosure controls and procedures with respect to its marketing of DSUVIA; (ii) as a  
26 result, AcelRx had been making false or misleading claims and representations about the risks and  
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1 beneath the tongue to dissolve. Marketing materials also touted that patients may retake the drug  
2 in one-hour intervals, without providing a maximum daily dosage.

3 20. On November 2, 2018, AcelRx announced that the FDA had approved DSUVIA  
4 for the management of acute pain in adults that is severe enough to require an opioid analgesic in  
5 certified medically supervised healthcare settings, such as hospitals, surgical centers, and  
6 emergency departments.  
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8 **Materially False and Misleading Statements Issued During the Class Period**

9 21. The Class Period begins on March 17, 2020, the day after AcelRx filed an annual  
10 report on Form 10-K with the SEC, during post-market hours, reporting the Company's financial  
11 and operating results for the quarter and year ended December 31, 2019 (the "2019 10-K"). The  
12 2019 10-K touted the Company's sales and marketing practices for DSUVIA, representing, *inter*  
13 *alia*, that Defendants have "created and deployed a focused scientific support team to gather a  
14 detailed understanding of individual emergency room and hospital needs in order to present  
15 DSUVIA effectively"; have "increased awareness of the clinical profile of sublingual  
16 administration of sufentanil through publication of our clinical data"; have "engaged appropriate  
17 Advisory Boards that include representative emergency room physicians, anesthesiologists,  
18 surgeons, nurses, pharmacy and therapeutics, or P&T, committee members and other related  
19 experts to provide us with input on appropriate commercial positioning for DSUVIA for each of  
20 these key audiences"; have "built a sales and marketing organization that can define appropriate  
21 segmentation and positioning strategies and tactics for DSUVIA"; and have "established DSUVIA  
22 on hospital and ambulatory surgery center formularies through deployment of an experienced team  
23 to explain the clinical and health economic attributes of DSUVIA."  
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1           22. The 2019 10-K also represented that Defendants “may adjust our  
2 commercialization plan” by, among other things, “continuing to build and progressively deploy a  
3 high-quality, customer-focused and experienced sales organization in the United States dedicated  
4 to bringing innovative, highly valued healthcare solutions to patients, payers and healthcare  
5 providers,” as needed, and by “continuing to establish DSUVIA as a suitable choice for moderate-  
6 to-severe acute pain in certified medically supervised settings.”  
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8           23. Additionally, the 2019 10-K touted that Defendants “have carried out an evaluation,  
9 under the supervision, and with the participation, of management including our principal executive  
10 officer and principal financial officer, of our disclosure controls and procedures . . . as of the end  
11 of the period covered by” the 2019 10-K, and that, “[b]ased on their evaluation, our principal  
12 executive officer and principal financial officer concluded that . . . our disclosure controls and  
13 procedures were effective as of December 31, 2019.”  
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15           24. Appended as exhibits to the 2019 10-K were signed certifications pursuant to the  
16 Sarbanes-Oxley Act of 2002 (“SOX”), wherein the Individual Defendants certified that “[t]he  
17 [2019 10-K] fully complies with the requirements of Section 13(a) or Section 15(d) of the  
18 Exchange Act” and that “[t]he information contained in the [2019 10-K] fairly presents, in all  
19 material respects, the financial condition and results of operations of the Company.”  
20

21           25. On May 11, 2020, AcelRx filed a quarterly report on Form 10-Q with the SEC,  
22 reporting the Company’s financial and operating results for the quarter ended March 31, 2020 (the  
23 “1Q20 10-Q”). The 1Q20 10-Q contained substantively the same statements as referenced in ¶  
24 23, *supra*, touting the effectiveness of the Company’s disclosure controls and procedures for the  
25 period covered by the report.  
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1           26. Appended as exhibits to the 1Q20 10-Q were substantively the same SOX  
2 certifications as referenced in ¶ 24, *supra*, signed by the Individual Defendants.

3           27. On August 10, 2020, AcelRx filed a quarterly report on Form 10-Q with the SEC,  
4 reporting the Company’s financial and operating results for the quarter ended June 30, 2020 (the  
5 “2Q20 10-Q”). The 2Q20 10-Q contained substantively the same statements as referenced in ¶  
6  
7 23, *supra*, touting the effectiveness of the Company’s disclosure controls and procedures for the  
8 period covered by the report.

9           28. Appended as exhibits to the 2Q20 10-Q were substantively the same SOX  
10 certifications as referenced in ¶ 24, *supra*, signed by the Individual Defendants.

11           29. On November 5, 2020, AcelRx filed a quarterly report on Form 10-Q with the SEC,  
12 reporting the Company’s financial and operating results for the quarter ended September 30, 2020  
13 (the “3Q20 10-Q”). The 3Q20 10-Q contained substantively the same statements as referenced in  
14 ¶ 23, *supra*, touting the effectiveness of the Company’s disclosure controls and procedures for the  
15 period covered by the report.  
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17           30. Appended as exhibits to the 3Q20 10-Q were substantively the same SOX  
18 certifications as referenced in ¶ 24, *supra*, signed by the Individual Defendants.

19           31. The statements referenced in ¶¶ 21-30 were materially false and misleading because  
20 Defendants made false and/or misleading statements, as well as failed to disclose material adverse  
21 facts about the Company’s business, operations, and compliance policies. Specifically,  
22 Defendants made false and/or misleading statements and/or failed to disclose that: (i) AcelRx had  
23 deficient disclosure controls and procedures with respect to its marketing of DSUVIA; (ii) as a  
24 result, AcelRx had been making false or misleading claims and representations about the risks and  
25 efficacy of DSUVIA in certain advertisements and displays; (iii) the foregoing conduct subjected  
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1 the Company to increased regulatory scrutiny and enforcement; and (iv) as a result, the Company's  
2 public statements were materially false and misleading at all relevant times.

### 3 The Truth Emerges

4 32. On February 16, 2021, AcelRx filed a current report on Form 8-K with the SEC,  
5 disclosing that, on February 11, 2021, AcelRx received a warning letter from the FDA concerning  
6 promotional claims for DSUVIA. Specifically, the Form 8-K disclosed, in relevant part:  
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8 On February 11, 2021, AcelRx . . . received a warning letter from the Office of  
9 Prescription Drug Promotion (“OPDP”) of the [FDA] (the “Letter”) relating to a  
10 banner advertisement the Company submitted to the OPDP on December 6, 2019  
11 (the “Banner Ad”), and a tabletop display the Company submitted on February 28,  
12 2020, and resubmitted to the OPDP at its request on September 23, 2020 (the  
13 “Tabletop Display,” and together with the Banner Ad, the “Promotional Material”).  
14 The Company submitted the materials to the OPDP pursuant to the FDA  
15 requirement that sponsors submit all promotional materials to the FDA at the time  
16 of their initial dissemination or publication. The FDA’s concerns identified in the  
17 Letter include its view that the Promotional Material makes misleading claims and  
18 representations about the risks and efficacy of DSUVIA® because the Promotional  
19 Material does not reveal facts that are material in light of the representations made  
20 . . . . [T]he Company has not used the Banner Ad since late 2019, nor used the table  
21 drape that is part of the Tabletop Display since November 2019; however, the  
22 Company plans to review its marketing materials to identify any potential revisions  
23 in light of the Letter. The Company intends to respond to the FDA within the  
24 timeframe requested in the Letter and seek guidance and clarification from the FDA  
25 on the concerns raised in the Letter. The Letter does not restrict the Company’s  
26 ability to manufacture or sell DSUVIA. The Company cannot give any assurances,  
27 however, that the FDA will be satisfied with its response to the Letter or that such  
28 response will resolve the issues identified in the Letter.

33. The FDA warning letter advised that the agency “has reviewed an ‘SDS Banner  
Ad’ (banner) (PM-US-DSV-0018) and a tabletop display (PM-US-DSV-0049) (display) for  
DSUVIA (sufentanil) sublingual tablet, CII (Dsuvia) submitted by AcelRx,” and that “[t]he  
promotional communications, the banner and display, make false or misleading claims and  
representations about the risks and efficacy of DSUVIA,” which “misbrand Dsuvia within the

1 meaning of the Federal Food, Drug and Cosmetic Act (FD&C Act) and make its distribution  
2 violative.”

3 34. Specifically, the FDA warning letter noted the following deficiency with respect to  
4 the banner and tabletop display at issue: “The banner includes the claim, ‘DSUVIA® comes in  
5 one strength for acute pain. . . **TONGUE AND DONE.**’ (bolded emphasis original; reference  
6 omitted) in conjunction with an image of the single-dose applicator device. Similarly, the display  
7 prominently includes the claim ‘**TONGUE AND DONE**’ (bolded emphasis original).” The FDA  
8 found that “[t]hese presentations are misleading because they imply that the administration of  
9 Dsuvia consists of a simple, one-step process, when this is not the case,” and that, “[i]n fact, there  
10 are numerous administration steps outlined in the PI [the FDA-approved product labeling],  
11 including a separate, distinct step to visually confirm tablet placement in the patient’s sublingual  
12 space of the mouth.”  
13

14 35. The FDA warning letter further advised that the banner at issue was deficient for  
15 stating “Minimum redosing interval **1 hour**” and “Average redosing interval **3 hours\*... \*Shown**  
16 over a 12-hour period in the pivotal trial” (emphases and alteration in original), because they  
17 “create a misleading impression about the use of Dsuvia” by “omit[ting] . . . material information  
18 from the DOSING AND ADMINISTRATION section of the PI.” Specifically, the banner should  
19 have included the words “Do not exceed 12 tablets in 24 hours” because, “[b]y omitting this  
20 material information about the maximum daily dosage, the banner creates a misleading impression  
21 about the safe use of Dsuvia.” The FDA noted that “[t]hese omissions are concerning from a  
22 public health perspective due to the serious risks associated with overdose with Dsuvia, including  
23 respiratory depression and death, that should be considered when prescribing the product.”  
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1           36.     Additionally, the FDA warning letter took issue with the banner’s claim that  
2 “DSUVIA® comes in one strength for acute pain” because “the banner makes representations  
3 about the indication and use of the drug but fails to adequately convey material information  
4 regarding Dsuvia’s limitations of use, thereby creating a misleading impression about the drug.”

5           37.     The FDA warning letter also found that, “unlike the benefit claims in the banner,  
6 which utilized a color background and large font, the full indication with the limitations of use are  
7 intermingled with risk information in a paragraph format in a much smaller font size and a plain  
8 white background,” which were only accessible to viewers by scrolling down the banner and,  
9 therefore, did “not mitigate the misleading impression.”  
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11           38.     The FDA warning letter further noted that the banner and tabletop display at issue  
12 “fail to present information relating to the Boxed Warning, Contraindications, Warnings and  
13 Precautions, and Adverse Reactions for Dsuvia with a prominence and readability reasonably  
14 comparable with the presentation of information relating to the benefits of Dsuvia.” The FDA  
15 warning letter found that “benefit claims for Dsuvia are presented in conjunction with colorful  
16 graphics and large bolded headlines, with significant white space,” whereas “the risk information  
17 is relegated farther down in paragraph format with less prominence.” The FDA therefore  
18 concluded that, “[b]y failing to adequately present the risks and benefits associated with Dsuvia,  
19 the banner and display create a misleading impression about the safe and effective use of the drug.”  
20

21           39.     Finally, the FDA warning letter “request[ed] that AcelRx cease any violations of  
22 the FD&C Act” and “submit a written response to th[e] letter within 15 days from the date of  
23 receipt.”  
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25           40.     On this news, AcelRx’s stock price fell \$0.21 per share, or 8.37%, to close at \$2.30  
26 per share on February 16, 2021.  
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1           45. Plaintiff will fairly and adequately protect the interests of the members of the Class  
2 and has retained counsel competent and experienced in class and securities litigation. Plaintiff has  
3 no interests antagonistic to or in conflict with those of the Class.

4           46. Common questions of law and fact exist as to all members of the Class and  
5 predominate over any questions solely affecting individual members of the Class. Among the  
6 questions of law and fact common to the Class are:  
7

- 8           • whether the federal securities laws were violated by Defendants' acts as alleged  
9           herein;
- 10           • whether statements made by Defendants to the investing public during the Class  
11           Period misrepresented material facts about the business, operations and  
12           management of AcelRx;
- 13           • whether the Individual Defendants caused AcelRx to issue false and misleading  
14           financial statements during the Class Period;
- 15           • whether Defendants acted knowingly or recklessly in issuing false and misleading  
16           financial statements;
- 17           • whether the prices of AcelRx securities during the Class Period were artificially  
18           inflated because of the Defendants' conduct complained of herein; and
- 19           • whether the members of the Class have sustained damages and, if so, what is the  
20           proper measure of damages.

21           47. A class action is superior to all other available methods for the fair and efficient  
22 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the  
23 damages suffered by individual Class members may be relatively small, the expense and burden  
24 of individual litigation make it impossible for members of the Class to individually redress the  
25 wrongs done to them. There will be no difficulty in the management of this action as a class action.

26           48. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-  
27 on-the-market doctrine in that:  
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- 1 • Defendants made public misrepresentations or failed to disclose material facts  
2 during the Class Period;
- 3 • the omissions and misrepresentations were material;
- 4 • AcelRx securities are traded in an efficient market;
- 5 • the Company's shares were liquid and traded with moderate to heavy volume  
6 during the Class Period;
- 7 • the Company traded on the NASDAQ and was covered by multiple analysts;
- 8 • the misrepresentations and omissions alleged would tend to induce a reasonable  
9 investor to misjudge the value of the Company's securities; and
- 10 • Plaintiff and members of the Class purchased, acquired and/or sold AcelRx  
11 securities between the time the Defendants failed to disclose or misrepresented  
12 material facts and the time the true facts were disclosed, without knowledge of the  
omitted or misrepresented facts.

13 49. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a  
14 presumption of reliance upon the integrity of the market.

15 50. Alternatively, Plaintiff and the members of the Class are entitled to the presumption  
16 of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v.*  
17 *United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in  
18 their Class Period statements in violation of a duty to disclose such information, as detailed above.

### 19 COUNT I

#### 20 **(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder** 21 **Against All Defendants)**

22 51. Plaintiff repeats and re-alleges each and every allegation contained above as if fully  
23 set forth herein.

24 52. This Count is asserted against Defendants and is based upon Section 10(b) of the  
25 Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.  
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1           53.     During the Class Period, Defendants engaged in a plan, scheme, conspiracy and  
2 course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions,  
3 practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other  
4 members of the Class; made various untrue statements of material facts and omitted to state  
5 material facts necessary in order to make the statements made, in light of the circumstances under  
6 which they were made, not misleading; and employed devices, schemes and artifices to defraud in  
7 connection with the purchase and sale of securities. Such scheme was intended to, and, throughout  
8 the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members,  
9 as alleged herein; (ii) artificially inflate and maintain the market price of AcelRx securities; and  
10 (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire AcelRx  
11 securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan  
12 and course of conduct, Defendants, and each of them, took the actions set forth herein.  
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15           54.     Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the  
16 Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly  
17 and annual reports, SEC filings, press releases and other statements and documents described  
18 above, including statements made to securities analysts and the media that were designed to  
19 influence the market for AcelRx securities. Such reports, filings, releases and statements were  
20 materially false and misleading in that they failed to disclose material adverse information and  
21 misrepresented the truth about AcelRx's finances and business prospects.  
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23           55.     By virtue of their positions at AcelRx, Defendants had actual knowledge of the  
24 materially false and misleading statements and material omissions alleged herein and intended  
25 thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants  
26 acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose  
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1 such facts as would reveal the materially false and misleading nature of the statements made,  
2 although such facts were readily available to Defendants. Said acts and omissions of Defendants  
3 were committed willfully or with reckless disregard for the truth. In addition, each Defendant  
4 knew or recklessly disregarded that material facts were being misrepresented or omitted as  
5 described above.  
6

7 56. Information showing that Defendants acted knowingly or with reckless disregard  
8 for the truth is peculiarly within Defendants' knowledge and control. As the senior managers  
9 and/or directors of AcelRx, the Individual Defendants had knowledge of the details of AcelRx's  
10 internal affairs.

11 57. The Individual Defendants are liable both directly and indirectly for the wrongs  
12 complained of herein. Because of their positions of control and authority, the Individual  
13 Defendants were able to and did, directly or indirectly, control the content of the statements of  
14 AcelRx. As officers and/or directors of a publicly-held company, the Individual Defendants had  
15 a duty to disseminate timely, accurate, and truthful information with respect to AcelRx's  
16 businesses, operations, future financial condition and future prospects. As a result of the  
17 dissemination of the aforementioned false and misleading reports, releases and public statements,  
18 the market price of AcelRx securities was artificially inflated throughout the Class Period. In  
19 ignorance of the adverse facts concerning AcelRx's business and financial condition which were  
20 concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise  
21 acquired AcelRx securities at artificially inflated prices and relied upon the price of the securities,  
22 the integrity of the market for the securities and/or upon statements disseminated by Defendants,  
23 and were damaged thereby.  
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1           62.     During the Class Period, the Individual Defendants participated in the operation  
2 and management of AcelRx, and conducted and participated, directly and indirectly, in the conduct  
3 of AcelRx’s business affairs. Because of their senior positions, they knew the adverse non-public  
4 information about AcelRx’s misstatement of income and expenses and false financial statements.

5           63.     As officers and/or directors of a publicly owned company, the Individual  
6 Defendants had a duty to disseminate accurate and truthful information with respect to AcelRx’s  
7 financial condition and results of operations, and to correct promptly any public statements issued  
8 by AcelRx which had become materially false or misleading.

9           64.     Because of their positions of control and authority as senior officers, the Individual  
10 Defendants were able to, and did, control the contents of the various reports, press releases and  
11 public filings which AcelRx disseminated in the marketplace during the Class Period concerning  
12 AcelRx’s results of operations. Throughout the Class Period, the Individual Defendants exercised  
13 their power and authority to cause AcelRx to engage in the wrongful acts complained of herein.  
14 The Individual Defendants, therefore, were “controlling persons” of AcelRx within the meaning  
15 of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct  
16 alleged which artificially inflated the market price of AcelRx securities.

17           65.     Each of the Individual Defendants, therefore, acted as a controlling person of  
18 AcelRx. By reason of their senior management positions and/or being directors of AcelRx, each  
19 of the Individual Defendants had the power to direct the actions of, and exercised the same to  
20 cause, AcelRx to engage in the unlawful acts and conduct complained of herein. Each of the  
21 Individual Defendants exercised control over the general operations of AcelRx and possessed the  
22 power to control the specific activities which comprise the primary violations about which Plaintiff  
23 and the other members of the Class complain.  
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