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U.S. EPA REGION IX
REGIONAL HEARING CLERK

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION IX

In the matter of:	)	U.S. EPA Docket No. CWA-09-2008-0002
BioMarin Pharmaceutical, Inc.	)	**CONSENT AGREEMENT AND FINAL ORDER**
Respondent.	)	

I. CONSENT AGREEMENT

A. INTRODUCTION

1. This civil administrative enforcement action was initiated pursuant Section 309(g) of the Clean Water Act ("CWA" or "Act"), 33 U.S.C. §1319(g), and 40 C.F.R. Part 22, "Consolidated Rules of the Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits."

2. Complainant is the United States Environmental Protection Agency, Region IX ("EPA"). Respondent is BioMarin Pharmaceutical, Inc., based in Novato, California ("Respondent" or "BioMarin").

3. The United States Environmental Protection Agency, Region 9 ("EPA") institutes this proceeding against BioMarin for alleged violations of the CWA's pretreatment requirements. CWA §307(d), 33 U.S.C. § 1317(d). This Consent Agreement and Final Order ("CA/FO") simultaneously commences and concludes this matter in accordance with 40 C.F.R. §§ 22.13(b) and 22.18(b).

4. The Respondent agrees that settlement of this matter without litigation is consistent with the provisions and objectives of the CWA and applicable regulations, that it is in the public interest, and that it is the most appropriate means of resolving this matter. The Respondent and EPA seek approval of the Consent Agreement and move for issuance of the accompanying Final Order.

5. NOW THEREFORE, before the taking of any testimony, without adjudication of any issue of fact or law, and upon consent and agreement of the parties to this Consent Agreement and Order, it is hereby AGREED, STIPULATED, and ORDERED:

B. ADMISSIONS AND WAIVERS

6. For purposes of this proceeding, Respondent admits and agrees that the EPA Administrator and Region IX Administrator have jurisdiction and authority over the subject matter of the action commenced in this CA/FO and over Respondent pursuant to Section 309(g) of the CWA, 33 U.S.C. § 1319(g), and 40 C.F.R. §§ 22.4 and 22.38. Further, for the purposes of this proceeding, Respondent admits to the jurisdictional allegations of facts and law set forth herein. Respondent consents to and agrees not to contest EPA's jurisdiction and authority to enter into and issue this CA/FO and to enforce its terms. Further, Respondent will not contest EPA's jurisdiction and authority to compel compliance with this CA/FO in any enforcement proceedings, either administrative or judicial, or to impose sanctions for violations of this CA/FO.

7. Respondent neither admits nor denies any allegations of fact or law set forth in the herein. Respondent hereby waives any rights Respondent may have to contest the allegations set forth herein, waives any rights Respondent may have to a hearing on any issue relating to the factual allegations or legal conclusions set forth herein, including without limitation a hearing pursuant to Section 309(g) of the CWA, 33 U.S.C. § 1319(g), and hereby consents to the issuance of this CA/FO without adjudication. In addition, Respondent hereby waives any rights Respondent may have to appeal the Final Order attached to this Consent Agreement and made part of this CA/FO.

8. This Consent Agreement contains the elements of a complaint required by 40 C.F.R. §§ 22.14(a)(1)-(3) and (8).

C. STATUTORY AND REGULATORY AUTHORITY

9. The objective of the Act is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters. 33 U.S.C. § 1251(a).

Pretreatment Program

10. CWA section 307, 33 U.S.C. § 1317, establishes the federal pretreatment program for regulating the introduction of wastewater from non-domestic sources into publicly owned

US EPA ARCHIVE DOCUMENT

treatment works ("POTW"). For purposes of CWA section 307, the term POTW includes the municipal wastewater treatment plant or works (including the reclamation plant) and its tributary sewer or conveyance systems. 40 C.F.R. § 403.3(q).

11. CWA section 307(d), 33 U.S.C. § 1317(d), prohibits the introduction of industrial pollutants into a POTW in violation of any pretreatment standards established pursuant to CWA section 307(b), 33 U.S.C. § 1317(b).

12. CWA section 307(b), 33 U.S.C. § 1317(b), directs EPA to publish regulations to establish pretreatment standards governing the introduction of industrial pollutants into POTWs. Pursuant to CWA section 307(b), EPA promulgated "General Pretreatment Regulations for Existing and New Sources of Water Pollution" at 40 C.F.R. Part 403. The General Pretreatment Regulations at 40 C.F.R. § 403.5 include national standards that prohibit certain discharges from all "industrial users," i.e., non-domestic sources regulated under CWA section 307 that introduce pollutants into a POTW. 40 C.F.R. §§ 403.1(b)(1), 403.3(h).

13. Under 40 C.F.R. § 403.5(b)(2), it is unlawful for an industrial user to introduce into a POTW pollutants that "will cause corrosive structural damage to the POTW, but in no case Discharges with pH lower than 5.0, unless the [treatment] works is specially designed to accommodate such Discharges." A violation of the low pH prohibition at 40 C.F.R. § 403.5(b)(2) is a violation of CWA section 307(d), 33 U.S.C. § 1317(d).

D. GENERAL ALLEGATIONS

14. BioMarin owns and operates a facility that specializes in producing enzymes to treat diseases and various medical conditions (the "Facility") at 46 Galli Drive, Novato, California, 94949.

15. At all times relevant to this action, BioMarin was a company incorporated in the State of Delaware, and thus a "person" under Section 502(5) of the CWA, 33 U.S.C. § 1362(5).

16. BioMarin's Facility discharges manufacturing process wastewater, clean-in-place washdown, ion exchange brine, reverse osmosis reject water, boiler blowdown, cooling tower blowdown, pump seal water, water discharge from lab sinks, washwater from regular sanitizing of floors/walls/ceilings, and domestic wastewater, and therefore introduces pollutants within the meaning of Section 502(6) of the Act, 33 U.S.C. § 1362(6), into the Novato Sanitary District ("NSD") domestic sewer system and Ignacio Wastewater Treatment Plant ("Ignacio POTW").

17. The NSD, Ignacio POTW and its tributary sewer systems are all POTWs under 40 C.F.R. § 403.3(g) and CWA section 307(b).

18. The Ignacio POTW, in combination with effluent from the Novato Wastewater

US EPA ARCHIVE DOCUMENT

Treatment Plant, discharges to the intertidal flats of San Pablo Bay. San Pablo Bay is a water of the United States under 40 C.F.R. § 122.2, which implements CWA section 502(7), 33 U.S.C. § 1362(7).

19. BioMarin's Facility operates under a discharge permit issued by NSD.

Pretreatment Violations at the Facility

20. As part of its production processes, the Facility generates and discharges an average of 8000 gallons per day to a maximum of 25,000 gallons per day of combined sanitary and industrial wastewater to the NSD sewer system and ultimately to the Ignacio POTW and San Pablo Bay. As an NSD industrial user, the Facility is subject to the federal low pH prohibition in 40 C.F.R. § 403.5(b)(2).

21. From January 2004 to October, 2007, BioMarin monitored the industrial wastewater effluent from its Facility using an automatic continuous pH sampler. BioMarin submitted its pH samples to the NSD. The results showed that BioMarin violated the federal low pH prohibition in 40 C.F.R. § 403.5(b)(2) and CWA section 307(d), 33 U.S.C. § 1317(d), by discharging low pH industrial wastewater from the Facility to the NSD sewer system, the Ignacio POTW, and ultimately San Pablo Bay, on sixty-two (62) days listed in the attached spreadsheet ("Attachment A").

22. Unauthorized discharges of pollutants to waters of the United States violates CWA section 307(d), 33 U.S.C. § 1317(d).

E. CIVIL PENALTY

23. Section 309(g)(2)(B) of the CWA, 33 U.S.C. § 1319(g)(2)(B), authorizes the administrative assessment of civil penalties in an amount not to exceed $10,000 per day for each day during which the violation continues, up to a maximum penalty of $125,000. Pursuant to the Debt Collection Improvement Act of 1996, 31 U.S.C. § 3701, and 40 C.F.R. Part 19, violations that occurred between January 30, 1997 and March 15, 2004 are subject to a penalty of up to $11,000 per day of violation, up to a maximum penalty of $137,500. Violations that occurred after March 15, 2004 are subject to a penalty of up to $11,000 per day of violation, up to a maximum penalty of $157,500. Based upon the facts alleged herein and upon those factors which the Complainant must consider pursuant to CWA section 309(g)(3), 33 U.S.C. § 1319(g)(3), and the EPA Supplemental Environmental Project Policy ("SEP Policy"), EPA has determined that it is appropriate to assess, and Respondent has, without admission, agreed to pay to the United States, a civil administrative penalty in the amount of $119,717.00.

US EPA ARCHIVE DOCUMENT

24. Payment of penalty must be received in accordance with one of the acceptable methods of payment in Paragraph 25 on or before **thirty (30) calendar days** after the effective date of the CA/FO. The date by which payment must be received by the United States shall be the "due date" for the payment.

25. Respondent shall make payment under this CA/FO in accordance with any of the acceptable methods of payment listed in the attached "EPA Region 9 Collection Information" sheet (Attachment B), which is incorporated by reference as part of this CA/FO. Concurrent with payment of the penalty, Respondent shall provide written notice of payment, referencing the title and docket number of this case and attach a photocopy of the penalty payment, via certified mail to each of the following:

Anna Yen
Environmental Engineer
Clean Water Act Compliance Office
U.S. EPA, Region IX
75 Hawthorne Street (Mail Code: WTR-7)
San Francisco, California 94105

Danielle Carr
Regional Hearing Clerk
U.S. EPA, Region IX
75 Hawthorne Street (Mail Code: ORC-1)
San Francisco, CA 94105

26. If the penalty is not paid when due, interest shall accrue on any overdue amount from the first date after the due date through the date of payment, at the interest rate established by the Secretary of the Treasury under 31 U.S.C. § 3717. In addition, a late payment handling charge of fifteen dollars ($15.00) will be assessed for each thirty (30) day period (or any portion thereof) following the due date in which the balance remains unpaid. Payment of any interest and late handling charges shall be made in accordance with paragraph 25 above.

27. Failure by Respondent to pay the full penalty when due entitles EPA and the United States to bring a civil action to recover the amount assessed. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review. In such an action, Respondent shall pay (in addition to any assessed penalty, interest, and monthly handling charges) attorney fees, costs for collection proceedings, and a quarterly nonpayment penalty for each quarter during which such failure to pay persists. Such nonpayment penalty shall be in an amount equal to twenty percent (20%) of the aggregate amount of Respondent's penalties and nonpayment penalties which are unpaid as of the beginning of such quarter. CWA section 309(g)(9), 33 U.S.C.§1319(g)(9).

28. The civil penalty, and any interest, late handling fees, or late penalty payments provided for in the CA/FO, shall not be deducted from Respondent's, or any affiliated entity's, federal, state or local taxes.

US EPA ARCHIVE DOCUMENT

F. SUPPLEMENTAL ENVIRONMENTAL PROJECT

29. As part of the settlement of this enforcement action, Respondent shall perform a Supplemental Environmental Project (SEP). Performance of all of the tasks set forth in this Section shall constitute satisfactory performance of the SEP.

30. Respondent shall implement a SEP to conduct stream restoration work to improve aquatic habitat, fish passage, and hydrologic function in Novato Creek and Vineyard Creek as further detailed in the proposed "Novato Creek Supplemental Environmental Project," attached to this CA/FO (Attachment C) and incorporated herein by reference. The restoration work is designed to achieve the following objectives:

a. Stabilize eroding banks and restore aquatic habitat function to creek and wetland ecosystems to improve habitat for endangered and threatened species; and
b. Restore native riparian and wetland vegetation to creek banks and wetlands, to achieve a success criteria of 80% survival of plantings.

31. Respondent certifies that its good faith estimate of the costs to implement this SEP are $50,270, and Respondent shall expend at least $50,270.00 on the SEP.

32. Respondent shall complete the restoration work within 36 months of the Effective Date of this CA/FO. Restored vegetation shall be maintained and monitored for three (3) years after the date of completion of the restoration work to ensure that the success criteria for restored vegetation (80% survival of plantings) is met by Respondent. Specifically, thirty (30) days following the end of the first six month period, and after each six month period, BioMarin shall submit a status report describing the previous six month's restoration and monitoring results, including photographs and other data. All submissions must be certified pursuant to 40 C.F.R. § 122.22(d).

33. Within 36 months after the Effective Date of this CA/FO, Respondent shall certify to EPA in writing that it has completed all SEP activities. At the same time, Respondent shall provide EPA an accounting showing the amount Respondent expended for the implementation of the SEP, and submit to EPA substantiating documentation, including but not limited to invoices, purchase orders, checks or receipts. All submittals under this SEP shall include the following statement signed by Respondent or its duly authorized representative in accordance with 40 CFR Section 122.22:

"I certify under penalty of law that this document and all attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, I certify that the information submitted is, to the best of my knowledge and belief, true, accurate, and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations."

US EPA ARCHIVE DOCUMENT

34. Any public statement, oral or written, in print, film, or other media, made by Respondent making reference to this SEP shall include the following language: "This project was undertaken in connection with the settlement of an enforcement action In the Matter of: BioMarin Pharmaceutical, Inc. Docket # CWA-09-2008-0002, taken on behalf of the United States Environmental Protection Agency, Region IX, under the Clean Water Act.

35. For Federal Income Tax purposes, Respondent agrees that it will neither capitalize into inventory or basis nor deduct any costs or expenditures incurred in performing the SEP.

36. In signing this CA/FO, Respondent hereby certifies that it is not required by any federal, state or local law or regulation to perform or develop the SEP described above; nor is Respondent required by agreement, grant or as injunctive relief in this or any other case (other than in this CA/FO) to perform or develop this SEP. Respondent certifies that no federal funding has been received or used, or will be received or used, for the SEP. Respondent certifies that it has not received, and is not presently negotiating to receive, credit in any other enforcement action for this SEP; nor will Respondent realize any profit, credit or tax deduction attributable to or associated with this SEP. Respondent further certifies that no funds will be used for education or student volunteer activities in carrying out the SEP.

G. DELAY IN PERFORMANCE AND STIPULATED PENALTIES

37. In addition to the interest and per annum penalties described in Paragraph 26, in the event that Respondent fails to pay the full amount of the penalty within the time specified in Paragraph 24, Respondent agrees to pay Complainant a stipulated penalty in the amount of up to $100.00 for each day the default continues.

38. Except as provided in paragraph 39 immediately below, in the event that Respondent fails to satisfactorily complete the SEP as required by this CA/FO, including all attachments, Respondent shall pay a stipulated penalty of $50,270.00.

39. If Respondent fails to satisfactorily complete the SEP as required by this CA/FO, including all attachments, but Respondent (a) has made good faith and timely efforts to complete the SEP; and (b) certifies, with supporting documentation, that at least 90% of the estimated costs committed to be expended on the SEP by this CAFO were spent, then no stipulated penalty will apply.

40. If Respondent satisfactorily completes the SEP in accordance with the requirements of this CA/FO, including all attachments, but Respondent spent less than 90% of the estimated costs committed to be expended on the SEP by this CAFO, Respondent shall pay a stipulated penalty of $10,054.00.

41. If Respondent satisfactorily completes the SEP in accordance with the requirements of this CA/FO, including all attachments, and spends at least 90% of the estimated costs committed to be expended on the SEP by this CAFO, no stipulated penalty will apply.

US EPA ARCHIVE DOCUMENT

42. The determination of whether Respondent has satisfactorily completed the SEP set forth in Section F of this CA/FO and the determination of whether Respondent has made a good faith, timely effort to implement the SEP for purposes of this Section, are within the sole discretion of the Director, Water Division, EPA Region IX, subject to the terms of this CA/FO. Upon request, EPA may provide Respondent with an opportunity to confer with the Division Director prior to this determination; however, such conference shall not provide Respondent with any rights to challenge or appeal the decision.

43. All stipulated penalties shall begin to accrue on the date that performance is due or a violation occurs. Stipulated penalties under paragraph 39 shall continue to accrue through the final day of correction of the noncompliance. Nothing herein shall prevent the simultaneous accrual of separate penalties for separate violations.

44. All stipulated penalties owed to EPA under this Section shall be due within thirty (30) days of receipt of a notification of noncompliance. Such notification shall describe the noncompliance and shall indicate the amount of penalties due. Interest at the current rate published by the United States Treasury, as described at 40 C.F.R. § 13.11, shall begin to accrue on the unpaid balance at the end of the thirty-day period.

45. Payment shall be made as described in paragraph 25. At the time payment is made, a copy of the check or payment documentation shall be sent to Danielle Carr and Anna Yen as described above in paragraph 25.

46. All payments shall indicate the Respondent's name and address, and the EPA docket number of this action.

47. The payment of stipulated penalties shall not alter in any way Respondent's obligation to complete the performance required hereunder.

48. The stipulated penalties set forth in this Section do not preclude EPA from pursuing any other remedies or sanctions which may be available to EPA by reason of Respondent's failure to comply with any of the requirements of this CA/FO. In any such an action, Respondent shall pay (in addition to any assessed penalty, interest, and monthly handling charges) attorney fees, and costs for collection proceedings.

H. PARTIES BOUND

49. This CA/FO shall apply to and be binding upon Respondent and its agents, successors and assigns and upon all persons acting under or for Respondent, until such time as the civil penalty required under Section E has been paid and either (1) the SEP required under Section F has been satisfactorily completed, or (2) in the event of failure to satisfactorily complete the SEP in full, satisfactory good-faith compliance pursuant to paragraph 39 has been made, or stipulated penalties in accordance with Section G of this CA/FO have been paid. At such time

US EPA ARCHIVE DOCUMENT

as those matters are concluded, this CA/FO shall terminate and constitute full settlement of the violations alleged herein.

50. No change in ownership or corporate, partnership or legal status relating to the Facility will in any way alter Respondent's obligations and responsibilities under this CA/FO.

51. Respondent shall give notice of this CA/FO to any successor in interest prior to transfer of ownership or operation of a substantial portion of Respondent's assets and shall notify EPA within seven (7) days prior to such transfer, until the termination of this CA/FO.

52. The undersigned representative of Respondent hereby certifies s/he is fully authorized by Respondent to enter into this CA/FO, to execute and to legally bind Respondent to it.

I. PUBLIC NOTICE

53. This Consent Agreement is subject to the requirements of CWA section 309(g)(4), 33 U.S.C. § 1319(g)(4), and 40 C.F.R. § 22.45(b), which provide for a thirty (30) day public notice of, and a reasonable opportunity for comment on, the Consent Agreement.

54. EPA reserves the right to withdraw from or withhold its consent to this Consent Agreement if public comment discloses material information that was not considered by EPA in entering into this Consent Agreement. In such case, Respondent's obligations under this document shall terminate, and EPA may pursue any and all enforcement options as provided by law. If no comment is timely received during the thirty (30) day comment period regarding the Consent Agreement, EPA shall file the Final Order.

55. This CA/FO shall take effect on the date the Final Order is filed with the Regional Hearing Clerk, and shall terminate when Respondent has complied with this CAFO in full.

J. GENERAL PROVISIONS

56. The Respondent knowingly and voluntarily enters into this Consent Agreement in full and final settlement of the civil administrative penalty liabilities for the specific alleged CWA violations alleged herein. Respondent has read the CA/FO, understands its terms, finds it to be reasonable, and consents to its terms and issuance of the Final Order, without admission of any factual or legal allegations.

57. This CA/FO, inclusive of all exhibits and attachments, is the entire agreement between EPA and the Respondent to resolve EPA's civil penalty claim against Respondent for the specific CWA violations alleged herein.

58. This CA/FO, and Respondent's full compliance with it, shall in no way affect the right of EPA or the United States to pursue any and all injunctive or other equitable relief or criminal sanctions for any violations of law, including but not limited to the right to bring further actions

US EPA ARCHIVE DOCUMENT

for matters not specifically alleged herein.

59. This CA/FO is not a permit, and it does not constitute a waiver, suspension or modification of the requirements of any federal, state, or local permit, or statute, ordinance, regulation, or order, including but not limited to any CWA requirements, permits or orders.

60. This CA/FO shall in no way affect the right of EPA or the United States against any third party (person/entity not a party to this CA/FO) or the right of any third party against Respondent. This CAFO does not create any right in or grant any cause of action to any third party.

61. EPA reserves any and all legal and equitable remedies available to enforce this CA/FO, and the right to seek recovery of any costs and attorney's fees incurred by EPA in any actions against Respondent for noncompliance with this CA/FO.

62. Except as set forth in paragraphs 27 and 48, EPA and the Respondent shall each bear their own costs and attorneys fees incurred in this proceeding.

63. Respondent agrees not to contest the validity of any terms and conditions set forth in this CA/FO in any action to enforce, or arising from, the CA/FO. Respondent waives, without any admission, any right to contest any issue of fact or law herein, or to seek a hearing, judicial review, or appeal of the Final Order.

64. This CA/FO shall take effect on the date the Final Order is filed with the Regional Hearing Clerk, and shall terminate when Respondent has complied with this CA/FO in full.

IT IS SO AGREED.

For BioMarin Pharmaceutical, Inc.:

4 August 2008
Date

G. Eric Davis
Vice President, General Counsel

For U.S. Environmental Protection Agency, Region IX:

8/4/08
Date

John Ong for
Alexis Strauss, Director
Water Division
U.S. Environmental Protection Agency, Region IX

US EPA ARCHIVE DOCUMENT

ATTACHMENT A

pH Violations

Year	Month	Date	pH Measurement	Low of the Month						No. of Violation Days Each Month
2004	March	3/22/2004	4.4	4.4						1
	April	4/7/2004	2.6	2.6						1
	July	7/18/2004	4.0	4.0						1
	October	10/14/2004	2.2	2.2						2
		10/22/2004	4.6							
	November	11/29/2004	3.7	3.7						1
	December	12/12/2004	3.95	2.9						5
		12/16/2004	4.2							
		12/17/2004	3.8							
		12/21/2004	2.9							
		12/22/2004	4.0							
2005	July	7/20/2005	3.8	3.8						1
	August	8/11/2005	4.2	3.2						4
		8/19/2005	4.4							
		8/26/2005	3.2							
		8/27/2005	4.8							
	October	*10/7/2005	4.2	2.2						4
		10/25/2005	2.2							
		10/27/2005	4.4							
		10/28/2005	4.4							
	November	11/8/2005	4.1	4.1						2
		11/15/2005	4.4							
	December	12/1/2005	4.0	2.8						3
		12/2/2005	2.8							
		12/30/2005	4.6							
2006	January	1/12/2006	3.8	3.8						3
		1/15/2006	3.8							
		1/25/2006	4.9							
	February	2/12/2006	3.0	3						4
		2/21/2006	4.5							
		2/26/2006	4.6							
		2/27/2006	3.2							
	March	3/2/2006	2.7	2.7						1
	April	4/30/2006	4.3	4.3						1
	May	5/23/2006	4.5	4.5						1
	July	7/13/2006	3.1	3.1						1
	August	8/24/2006	4.9	4.9						1
	September	9/1/2006	4.9	4.4						2
		9/19/2006	4.4							
	December	**12/14/200	4.7	1.3						2
		***12/17/20	1.3							
2007	February	2/4/2007	4.4	4						5
		2/16/2007	4.5							
		2/21/2007	4.5							
		2/23/2007	4.0							
		2/28/2007	4.2							
	March	3/8/2007	1.1	1.1						1

US EPA ARCHIVE DOCUMENT

pH Violations

Year	Month	Date	pH Measurement	Low of the Month						No. of Violation Days Each Month
	April	4/12/2007	2.8	2.8						2
		4/18/2007	4.0							
	May	5/3/2007	3.5	3.5						1
	June	6/8/2007	4.3	3.1						2
		6/25/2007	3.1							
	July	7/30/2007	2.2	2.2						1
	August	8/5/2007	4.1	2.5						5
		8/8/2007	2.5							
		8/11/2007	4.0							
		8/19/2007	4.0							
		8/24/2007	3.3							
	September	9/12/2007	4.6	4.6						2
		9/29/2007	4.8							
	October	10/14/2007	2.6	2.6						2
		10/15/2007	4.1							
								TOTAL:		62
*	Debris around the probe									
**	Probe failure									
***	A faulty preamp									

US EPA ARCHIVE DOCUMENT

US EPA ARCHIVE DOCUMENT

ATTACHMENT B

In the Matter of

BioMarin Pharmaceutical, Inc.

EPA Docket No. CWA-09-2008-xxxx

EPA REGION 9 COLLECTION INFORMATION:

ELECTRONIC FUNDS TRANSFERS

Federal Reserve Bank of New York
ABA = 021030004
Account = 68010727
SWIFT address = FRNYUS33
33 Liberty Street
New York, NY 10045
Field Tag 4200 of the Fedwire message should read:
"D 68010727 Environmental Protection Agency "

CHECK PAYMENTS

If payment is made by check, the check should be made payable to the "Treasurer, United States of America"

U.S. Environmental Protection Agency
Fines and Penalties
Cincinnati Finance Center
P.O. Box 979077
St. Louis, MO 63197-9000

OVERNIGHT MAIL:

U.S. Bank
1005 Convention Plaza
Mail Station SL-MO-C2GL
St. Louis, MO 63101

Contact: Natalie Pearson
314-418-4087

US EPA ARCHIVE DOCUMENT

ATTACHMENT C

Novato Creek Supplemental Environmental Project ("SEP")

BioMarin Pharmaceutical shall implement the following SEP as a component of settlement of alleged Clean Water Act violations at its facility in Novato, California. The SEP shall consist of stream restoration work in Novato Creek and one of its tributaries, Vineyard Creek, to improve aquatic habitat, fish passage, and hydrologic function. The SEP will complement a larger long-term multi-stakeholder driven process. Currently, the Marin County Public Works Department is engaged in a large-scale restoration of the Novato Creek watershed. BioMarin certifies that the restoration work in this SEP would not otherwise occur as part that effort.

Novato Creek suffers from poor water quality that is a result of, among other things, untreated and treated industrial waste discharges into the watershed. The presence of non-native species is one of the best documented indicators of degraded ecosystems. Non-native species tend to do better in degraded habitats, including those that have been degraded by poor water quality. On their own, the presence of non-native species can also be harmful to the ecosystem. These species crowd out native plants and provide substandard food and shelter for native plant and animal species. Removal of non-native plants gives native plants a better chance to become established. These native plants, in turn, help to significantly improve water quality.

BioMarin shall implement this SEP restoration work to achieve the following objectives:

(1) Stabilize eroding banks and restore functioning habitats to creek and wetland ecosystems to improve habitat for steelhead salmon and the Northwest Pond Turtle, two endangered and threatened species;

(2) Restore native vegetation to creek banks and wetlands; and

(3) Improve water quality that has been degraded over time by, among other things, industrial wastewater discharges.

For the restoration work in Novato Creek and Vineyard Creek, BioMarin shall remove invasive English ivy (*Hedera helix*) and Vinca sp and revegetate at least 1,000

linear feet with 150 native plants including California buckeye, coffeeberry, and California rose.

For the revegetation, BioMarin shall plant willows and other native trees and shrubs. Plants shall be propagated locally to maintain the original genetic make-up of the watershed, and shall be protected from deer and other foragers by biodegradable plastic protectors and from weeds by weed mats. BioMarin shall visit sites regularly during the dry season for weeding, checking irrigation, and collecting monitoring data. BioMarin shall maintain and monitor the plants for a three-year establishment period. At the end of this time, BioMarin shall ensure that the plantings show an 80% survival rate.

Depending on the specific restoration sites selected, BioMarin may also install biotechnical erosion control structures, such as brush check dams, willow walls or willow *fascines* (cigar-shaped bundles), and/or may install creek bank revegetation with willow sprigs or native trees and shrubs from containers. BioMarin shall install biotechnical structures as early as possible to provide as much erosion control in the first year and to utilize the rains to promote plant rigor before the dry season begins. As living structures, these willow walls should continue to improve water quality as they mature and their root systems extend each subsequent year.

BioMarin shall also implement a robust maintenance and monitoring program, including weeding, watering, data monitoring, and adaptive management (i.e., identifying factors contributing to plant mortality and undertaking actions, including revegetation where appropriate, to address findings). With regard to monitoring, BioMarin shall label each newly propagated tree and shrub with a tag when it is planted. In the late summer or early fall, BioMarin shall examine each tree or shrub for the following parameters: qualitative vigor rating, browse level, and evidence of damage. BioMarin shall use the plant labels to track the growth success by plant and species for each site. In addition, BioMarin shall conduct photomonitoring following state protocols (Standard Operating Procedure 4.2.1.4). Specifically, Bio Marin shall select photo points on the restoration day or shortly thereafter and record the points using a Global Positioning System. BioMarin shall return to each exact photo spot once per year for three years to monitor overall growth of the restoration site.

Thirty (30) days following the end of the first six month period and after each subsequent six month period, BioMarin shall submit a status report describing the previous six months' restoration and monitoring results, including photographs and

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other data. All submissions must be certified pursuant to 40 C.F.R. § 122.22(d). This requirement shall be set forth in Paragraph #32 of the Consent Agreement.

BioMarin is responsible for implementing this SEP but may contract with third party consultants. BioMarin expects to contract with The Bay Institute ("TBI") to carry out the SEP. TBI has extensive experience in carrying out restorations with professional and contracting staff. TBI staff is expected to carry out the proposed restoration in collaboration with its subcontractor, Prunuske Chatham, Inc. ("PCI"), and The Marin Conservation Corps ("MCC"). MCC will be nominally involved in the role of providing professional (not volunteer) restoration assistance to TBI. TBI understands that no funds allocated for the Novato Creek Watershed Project may be used for any work other than that proposed above, and, in particular, that no funds may be used for education or student volunteer activities by TBI, PCI, or the Marin Conservation Corps in carrying out the proposed Project. This restriction will be memorialized in Paragraph #36 of the Consent Agreement.

TBI's contractor for this work is expected to be PCI. PCI is an environmental engineering firm that specializes in ecological restoration, hydrology, revegetation, and erosion control, and has been designing and implementing restoration work for TBI for over 16 years. TBI works with foresters, landscape designers, and biologists from PCI to plan and design stream restorations. Harold Appleton, a certified forester, is the Project Leader for PCI.

BioMarin estimates that the work described will cost just over $50,000. BioMarin shall pay for any additional work or materials that are needed to ensure the long-term success of the proposed SEP.

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II. FINAL ORDER

IT IS HEREBY ORDERED that this Consent Agreement and Final Order pursuant to 40 C.F.R. § 22.18, U.S. EPA Docket No. CWA-09-2008-0002, be entered and that Respondent, BioMarin Pharmaceutical, Inc., complete the Supplemental Environmental Project and all other tasks required under this CA/FO (including, if applicable, the payment of any additional civil penalty which may become due under Section E of this CA/FO), and pay a civil penalty of **$119,717.00**. Payment shall be made pursuant to **paragraph 25** of the CA/FO within thirty (30) days of the Effective Date. A copy of the check or payment documentation shall be sent to the EPA Region IX addresses specified in Section E of this Consent Agreement and Final Order pursuant to 40 C.F.R. § 22.18 at such time as payment is made.

This Final Order shall be effective immediately.

09/04/08
Date

Steven Jawgiel
Regional Judicial Officer
U.S. Environmental Protection Agency, Region IX

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CERTIFICATION OF SERVICE

I certify that the original and the foregoing Consent Agreement and Final Order in the matter of BioMarin Pharmaceutical, Inc., **Docket Number CWA-~~9~~ 09-2008-** 0002 **0002**, has been filed with the Regional Hearing Clerk and that copies were sent return receipt requested to the following:

Mr. G. Eric Davis
Vice President, General Counsel
BioMarin Pharmaceutical, Inc.
105 Digital Drive
Novato, California 94949

Certified Mail No.:
7000 0520 0021 6108 1643

September 9, 2008

Danielle E. Carr

Danielle Carr
Regional Hearing Clerk
U.S. Environmental Protection Agency
Region IX
75 Hawthorne Street (ORC-1)
San Francisco, CA 94105

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