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UPDATE

REORIENTING BAYH-DOLE'S MARCH-IN: LOOKING TO PURPOSE AND OBJECTIVES IN THE PUBLIC'S INTEREST

BY ABIGAIL AMATO RIVES

In light of developments since publication, this addendum updates the article *Reorienting Bayh-Dole's March-In: Looking to Purpose and Objectives in the Public's Interest*.¹ In that article, the author suggested practical changes to the implementation of the Bayh-Dole Act which would allow the government to address public health concerns regarding access to federally funded medical technologies.² This addendum describes the outcome of a recent agency decision under the Bayh-Dole Act. This recent development does not alter the author's previous argument. However, in light of recent agency action, it seems that Congressional intervention or new regulations developed by the Department of Commerce will be necessary to implement the author's suggestion.

On October 25, 2012, four non-profit organizations petitioned the National Institutes of Health ("NIH"), requesting that the agency march-in on six of Abbott's patents relating to the drug ritonavir (brand name "Norvir").³ The four non-profits involved felt that the

1. Abigail Amato Rives, *Reorienting Bayh-Dole's March-In: Looking to Purpose and Objectives in the Public's Interest*, 5 AM. U. INTELL. PROP. BRIEF 77 (2013).

2. *Id.*

3. KNOWLEDGE ECOLOGY INTERNATIONAL, REQUEST FOR MARCH-IN ON ABBOTT PATENTS FOR RITONAVIR ON GROUNDS THAT ABBOTT PRIVATE SECTOR PRICES FOR RITONAVIR ARE HIGHER THAN IN OTHER HIGH INCOME COUNTRIES AND ABBOTT'S REFUSAL TO LICENSE PATENTS FOR NON-ABBOTT FIXED DOSE COMBINATIONS OF HIV DRUGS 3 [hereinafter NORVIR PETITION 2012] (Oct. 25, 2012), available at http://keionline.org/sites/default/files/2012_Oct25_Ritonavir_march_in_complaint.pdf.

price of Norvir is (still) too high in the United States—especially when compared to the price in other high-income countries—and that Abbott’s refusal to license the patents was detrimental to both individual patients and public health.⁴ This petition also asked the NIH to implement new policies which would allow the agency to leverage the power of the purse, to the extent possible, to control high drug prices.⁵ After over a year of deliberations, the NIH denied the march-in request.⁶ This was the second such request made, and denied, regarding ritonavir.⁷

These organizations were seeking to use the unique statutory mechanism of “march-in.”⁸ As a reminder, the Bayh-Dole Act allows research institutions to patent inventions that arise from federally funded research.⁹ Through the Act, the government retains the right to “march-in.”¹⁰ This means that the government can issue licenses for the patented technology if patent-holders are not taking reasonable steps to realize the public benefit of the federally funded research.¹¹ In theory at least, march-in would increase competition (including generic competition in the pharmaceutical market), lower prices, and allow follow-on innovation.¹²

The NIH has received five petitions asking it to march-in,¹³ and each time the agency has declined.¹⁴ It has used the exact same reasoning in responding to all five petitions.¹⁵ The NIH engages in a rigid interpretation of the march-in provision;¹⁶ only considering

4. NORVIR PETITION 2012, *supra* note 47, at 3-4.

5. NORVIR PETITION 2012, *supra* note 47, at 2-3.

6. NATIONAL INSTITUTES OF HEALTH OFFICE OF THE DIRECTOR DETERMINATION IN THE CASE OF NORVIR® MANUFACTURED BY ABBVIE 1 (Nov. 1, 2013) [hereinafter NIH DETERMINATION], available at <http://www.otl.nih.gov/sites/default/files/documents/policy/March-In-Norvir2013.pdf>.

7. See ESSENTIAL INVENTIONS, INC., PETITION TO USE AUTHORITY UNDER BAYH-DOLE ACT TO PROMOTE ACCESS TO RITONAVIR, SUPPORTED BY NATIONAL INSTITUTE OF ALLERGY AND INFECTIONS DISEASES CONTRACT NO. A127220 (Jan. 29 2004) [hereinafter NORVIR PETITION 2004], available at <http://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf>.

8. 35 U.S.C. § 203 (2012).

9. *Id.* § 202.

10. *Id.* § 203.

11. *Id.*

12. Rives, *supra* note 1, at 80.

13. *Id.* at 81.

14. *Id.*; NIH DETERMINATION, *supra* note 50.

15. Rives, *supra* note 1, at 88.

16. *Id.* at 88. In the 2012 request, petitioners also requested march-in under 35 U.S.C. § 203(a)(3). That provision of the statute deals with actions that are necessary to comply with other Federal regulations. The NIH rejected that argument because neither the Americans with Disabilities Act nor the Patient Protection and Affordable

whether patent-holders are taking effective steps to achieve practical application of an invention¹⁷ and whether march-in would relieve unfulfilled health and safety needs.¹⁸ If a drug is on the market, with FDA approval, and being manufactured, that satisfies the “practical application” element of the statute.¹⁹ Similarly, if a drug is FDA approved, and being prescribed to treat patients, that satisfies the “health and safety needs” element of the statute.²⁰

In its most recent determination, the NIH rejected the claims (1) that Abbott failed to achieve practical application of Norvir and (2) that Abbott was failing to satisfy health and safety needs.²¹ Norvir is an FDA-approved drug, it is co-administered with other marketed drugs, and there is no evidence that it is in short supply.²² There are even Norvir-containing drugs provided through the President’s Emergency Plan for AIDS Relief (“PEPFAR”) and similar drugs in the pipeline.²³ This “record of manufacture and ritonavir’s availability and use around the world demonstrate[d]” to NIH that Abbott was achieving practical application of the invention.²⁴ Regarding health and safety needs, this same evidence indicates that Abbott is meeting the demand for Norvir.²⁵ The price of the drug is not increasing, and there are patient assistant programs through which low-income patients can access Norvir.²⁶ No information was provided to suggest Abbott “has failed to ‘reasonably satisfy’ the health and safety need standard of the Bayh-Dole march-in statute.”²⁷

In the earlier article, the author suggested that the government should consider the purpose and objectives of the Bayh-Dole Act, and give weight to the public’s interest, when making a march-in decision.²⁸ Congress included march-in in the Bayh-Dole Act as a safety valve to protect the public interest.²⁹ Importantly, march-in was intended to combat misuse of federally funded inventions where a patent-holder was using a technology in a way that was antithetical to

Care Act require the use of Ritonavir. NIH DETERMINATION, *supra* note 50, at 5. Analysis of this provision is outside the scope of this paper.

17. 35 U.S.C. § 203(a)(1) (2012).

18. *Id.* § 203(a)(2).

19. See, e.g., NIH DETERMINATION, *supra* note 50, at 4.

20. See, e.g., NIH DETERMINATION, *supra* note 50, at 4-5.

21. NIH DETERMINATION, *supra* note 50, at 4.

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.* at 5.

28. Rives, *supra* note 1, at 77-78.

29. *Id.* at 81.

public benefits.³⁰ For example, there is evidence that Abbott increased the price of Norvir to preserve the position of another product in the market.³¹ The company sought to limit use of Norvir and thereby increase use of another product—which is directly opposed to the goals of the Bayh-Dole Act.³²

The author suggested that federal research funding agencies, such as the NIH, should consider two additional factors when weighing a march-in decision: (1) are patent-holders acting consistent with the purposes and objectives of the Bayh-Dole Act and (2) would march-in promote the public interest?³³ If patent holders are not acting consistent with the purposes of Bayh-Dole, this would indicate that march-in is appropriate. If march-in would not serve a public interest, then march-in is probably not appropriate. The author also described three possible avenues for implementing this new approach. NIH could issue interpretive guidance elaborating a new march-in approach;³⁴ the Department of Commerce could revise its regulations implementing Bayh-Dole;³⁵ or Congress could amend the Act to announce this shift in march-in.³⁶

The NIH could, and still can, incorporate the Act's purpose and objectives into future march-in decisions.³⁷ However, especially based on the recent NIH determination, it seems clear that the agency will continue to apply the same decision-making framework.³⁸ There are benefits to agency consistency; the community will know what to expect from the agency when it makes future march-in determinations.³⁹ Furthermore, courts tend to reward agency consistency.⁴⁰ The NIH would not want to have its march-in decision overturned on judicial review, which makes it harder to deviate from its previous decisions.

Therefore, if the government wants to adopt the author's suggested march-in approach, Congress or the Department of Commerce will have to act. The Department of Commerce should revise the regulations implementing Bayh-Dole, reemphasizing that agencies ought to consider the purpose and objectives of the Act

30. *Id.* at 77-78.

31. *Id.* at 80.

32. *Id.* at 112-13.

33. *Id.* at 101.

34. *Id.* at 106.

35. *Id.* at 110.

36. *Id.* at 111.

37. *Id.* at 106.

38. See, e.g., NIH DETERMINATION, *supra* note 50.

39. See Rives, *supra* note 1, at 107-8.

40. See, e.g., *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

when deciding whether to initiate march-in proceedings.⁴¹ Congressional amendment of the Bayh-Dole Act would be the most decisive way to reorient the march-in provision.⁴² Congress can send a clear signal to agencies like the NIH that march-in decisions should be made in the context of Bayh-Dole's broader objective to promote the public's interests.⁴³

So far, the march-in provision has failed to be an effective safety valve in the overall Bayh-Dole framework. It was intended to deter or correct misuse of federally funded technologies.⁴⁴ The recent NIH determination regarding ritonavir signals that the agency will not shift the march-in process. This reemphasizes the argument from the earlier paper and suggests we need to look to Congress or the Department of Commerce to reorient the march-in provision and ensure there is a viable safety valve in the Bayh-Dole Act to protect the public's interest.⁴⁵

In that article, the author suggested practical changes to the implementation of the Bayh-Dole Act which would allow the government to address public health concerns regarding access to federally funded medical technologies.⁴⁶ This addendum describes the outcome of a recent agency decision under the Bayh-Dole Act. This recent development does not alter the author's previous argument. However, in light of recent agency action, it seems that Congressional intervention or new regulations developed by the Department of Commerce will be necessary to implement the author's suggestion.

On October 25, 2012, four non-profit organizations petitioned the National Institutes of Health ("NIH"), requesting that the agency march-in on six of Abbott's patents relating to the drug ritonavir (brand name "Norvir").⁴⁷ The four non-profits involved felt that the price of Norvir is (still) too high in the United States—especially when compared to the price in other high-income countries—and that Abbott's refusal to license the patents was detrimental to both individual patients and public health.⁴⁸ This petition also asked the NIH to implement new policies which would allow the agency to leverage the power of the purse, to the extent possible, to control

41. Rives, *supra* note 1, at 110.

42. *Id.* at 111.

43. *Id.*

44. *Id.* at 86-87.

45. Rives, *supra* note 1, at 77.

46. *Id.*

47. NORVIR PETITION 2012, *supra* note 3, at 3.

48. *Id.* at 3-4.

high drug prices.⁴⁹ After over a year of deliberations, the NIH denied the march-in request.⁵⁰ This was the second such request made, and denied, regarding ritonavir.⁵¹

These organizations were seeking to use the unique statutory mechanism of “march-in.”⁵² As a reminder, the Bayh-Dole Act allows research institutions to patent inventions that arise from federally funded research.⁵³ Through the Act, the government retains the right to “march-in.”⁵⁴ This means that the government can issue licenses for the patented technology if patent-holders are not taking reasonable steps to realize the public benefit of the federally funded research.⁵⁵ In theory at least, march-in would increase competition (including generic competition in the pharmaceutical market), lower prices, and allow follow-on innovation.⁵⁶

The NIH has received five petitions asking it to march-in,⁵⁷ and each time the agency has declined.⁵⁸ It has used the exact same reasoning in responding to all five petitions.⁵⁹ The NIH engages in a rigid interpretation of the march-in provision,⁶⁰ only considering whether patent-holders are taking effective steps to achieve practical application of an invention⁶¹ and whether march-in would relieve unfulfilled health and safety needs.⁶² If a drug is on the market, with FDA approval, and being manufactured, that satisfies the “practical application” element of the statute.⁶³ Similarly, if a drug is FDA approved, and being prescribed to treat patients, that satisfies the “health and safety needs” element of the statute.⁶⁴

In its most recent determination, the NIH rejected the claims (1)

49. NORVIR PETITION 2012, *supra* note 47, at 2-3.

50. NIH DETERMINATION, *supra* note 6, at 1.

51. See NORVIR PETITION 2004, *supra* note 7.

52. 35 U.S.C. § 203 (2012).

53. *Id.* § 202.

54. *Id.* § 203.

55. *Id.*

56. Rives, *supra* note 1, at 80.

57. *Id.* at 81.

58. *Id.*; NIH DETERMINATION, *supra* note 50.

59. Rives, *supra* note 1, at 88.

60. *Id.* at 88. In the 2012 request, petitioners also requested march-in under 35 U.S.C. § 203(a)(3). That provision of the statute deals with actions that are necessary to comply with other Federal regulations. The NIH rejected that argument because neither the Americans with Disabilities Act nor the Patient Protection and Affordable Care Act require the use of Ritonavir. NIH DETERMINATION, *supra* note 50, at 5. Analysis of this provision is outside the scope of this paper.

61. 35 U.S.C. § 203(a)(1) (2012).

62. *Id.* § 203(a)(2).

63. See, e.g., NIH DETERMINATION, *supra* note 50, at 4.

64. See, e.g., *Id.* at 4-5.

that Abbott failed to achieve practical application of Norvir and (2) that Abbott was failing to satisfy health and safety needs.⁶⁵ Norvir is an FDA-approved drug, it is co-administered with other marketed drugs, and there is no evidence that it is in short supply.⁶⁶ There are even Norvir-containing drugs provided through the President's Emergency Plan for AIDS Relief ("PEPFAR") and similar drugs in the pipeline.⁶⁷ This "record of manufacture and ritonavir's availability and use around the world demonstrate[d]" to NIH that Abbott was achieving practical application of the invention.⁶⁸ Regarding health and safety needs, this same evidence indicates that Abbott is meeting the demand for Norvir.⁶⁹ The price of the drug is not increasing, and there are patient assistance programs through which low-income patients can access Norvir.⁷⁰ No information was provided to suggest Abbott "has failed to 'reasonably satisfy' the health and safety need standard of the Bayh-Dole march-in statute."⁷¹

In the earlier article, the author suggested that the government should consider the purpose and objectives of the Bayh-Dole Act, and give weight to the public's interest, when making a march-in decision.⁷² Congress included march-in in the Bayh-Dole Act as a safety valve to protect the public interest.⁷³ Importantly, march-in was intended to combat misuse of federally funded inventions where a patent-holder was using a technology in a way that was antithetical to public benefits.⁷⁴ For example, there is evidence that Abbott increased the price of Norvir to preserve the position of another product in the market.⁷⁵ The company sought to limit use of Norvir and thereby increase use of another product—which is directly opposed to the goals of the Bayh-Dole Act.⁷⁶

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65. *Id.* at 4.

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.* at 5.

72. Rives, *supra* note 1, at 77-78.

73. *Id.* at 81.

74. *Id.* at 77-78.

75. *Id.* at 80.

76. *Id.* at 112-13.

promote the public interest?⁷⁷ If patent holders are not acting consistent with the purposes of Bayh-Dole, this would indicate that march-in is appropriate. If march-in would not serve a public interest, then march-in is probably not appropriate. The author also described three possible avenues for implementing this new approach. NIH could issue interpretive guidance elaborating a new march-in approach;⁷⁸ the Department of Commerce could revise its regulations implementing Bayh-Dole;⁷⁹ or Congress could amend the Act to announce this shift in march-in.⁸⁰

The NIH could, and still can, incorporate the Act's purpose and objectives into future march-in decisions.⁸¹ However, especially based on the recent NIH determination, it seems clear that the agency will continue to apply the same decision-making framework.⁸² There are benefits to agency consistency; the community will know what to expect from the agency when it makes future march-in determinations.⁸³ Furthermore, courts tend to reward agency consistency.⁸⁴ The NIH would not want to have its march-in decision overturned on judicial review, which makes it harder to deviate from its previous decisions.

Therefore, if the government wants to adopt the author's suggested march-in approach, Congress or the Department of Commerce will have to act. The Department of Commerce should revise the regulations implementing Bayh-Dole, reemphasizing that agencies ought to consider the purpose and objectives of the Act when deciding whether to initiate march-in proceedings.⁸⁵ Congressional amendment of the Bayh-Dole Act would be the most decisive way to reorient the march-in provision.⁸⁶ Congress can send a clear signal to agencies like the NIH that march-in decisions should be made in the context of Bayh-Dole's broader objective to promote the public's interests.⁸⁷

So far, the march-in provision has failed to be an effective safety valve in the overall Bayh-Dole framework. It was intended to deter or

77. *Id.* at 101.

78. *Id.* at 106.

79. *Id.* at 110.

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82. See, e.g., NIH DETERMINATION, *supra* note 50.

83. See Rives, *supra* note 1, at 107-8.

84. See, e.g., *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).

85. Rives, *supra* note 1, at 110.

86. *Id.* at 111.

87. *Id.*

correct misuse of federally funded technologies.⁸⁸ The recent NIH determination regarding ritonavir signals that the agency will not shift the march-in process. This reemphasizes the argument from the earlier paper and suggests we need to look to Congress or the Department of Commerce to reorient the march-in provision and ensure there is a viable safety valve in the Bayh-Dole Act to protect the public's interest.

88. *Id.* at 86-87.

