

# The Burger Court Opinion Writing Database

*United States v. Generix Drug Corp.*

460 U.S. 453 (1983)

Paul J. Wahlbeck, George Washington University  
James F. Spriggs, II, Washington University in St. Louis  
Forrest Maltzman, George Washington University



Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
THE CHIEF JUSTICE

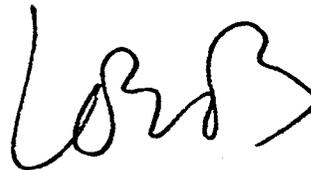
March 9, 1983

Re: No. 81-1222, United States v. Generix Drug Corp.

Dear John:

I join.

Regards,

A handwritten signature in black ink, appearing to be 'L. Stevens', written in a cursive style.

Justice Stevens

Copies to the Conference

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE WM. J. BRENNAN, JR.

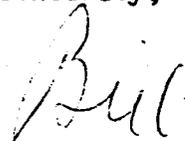
March 2, 1983

RE: No. 81-1222 United States v. Generix Drug Corporation

Dear John:

I agree.

Sincerely,



Justice Stevens

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Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE BYRON R. WHITE

March 3, 1983

Re: 81-1222 - United States  
v. Generix Drug Corp.

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Dear John,

I join.

Sincerely,



Justice Stevens

Copies to the Conference

cpm

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE THURGOOD MARSHALL

March 3, 1983

Re: No. 81-1222 - U.S. v. Generix Drug Corp.

Dear John:

Please join me.

Sincerely,

*JM.*

T.M.

Justice Stevens

cc: The Conference

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE HARRY A. BLACKMUN

March 4, 1983

Re: No. 81-1222, United States v. Generix Drug Corp.

Dear John:

I shall be with you in the result in this case, but I obviously have more difficulty with the litigation than you, and the others who have so quickly joined you. I shall try to get my separate writing around before too much delay.

Sincerely,



Justice Stevens

cc: The Conference

To: The Chief Justice  
Justice Brennan  
Justice White  
Justice Marshall  
Justice Powell  
Justice Rehnquist  
Justice Stevens  
Justice O'Connor

From: **Justice Blackmun**

Circulated: MAR 11 1983

Recirculated: \_\_\_\_\_

1st DRAFT

**SUPREME COURT OF THE UNITED STATES**

No. 81-1222

**UNITED STATES, PETITIONER v. GENERIX  
DRUG CORPORATION ET AL.**

**ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF  
APPEALS FOR THE ELEVENTH CIRCUIT**

[March —, 1983]

**JUSTICE BLACKMUN, concurring in the judgment.**

I

The question in this case is whether respondent may market generic drug products without filing for each product a new drug application pursuant to § 505(a) of the Federal Food, Drug, and Cosmetic Act (Act), 52 Stat. 1052, as amended, 21 U. S. C. § 355(a).

As the Court recognizes, the answer to this question depends upon the meaning of the term "drug" in § 201(g)(1) of the Act, as amended, 21 U. S. C. § 321(g)(1). That section reads:

"The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories."

HAB

March 16, 1983

Re: No. 81-1222 - United States v. Generix Drug Corp.

Dear John:

Your proposed redraft alleviates my concerns, and, if it is circulated, I shall join it. I shall then withdraw my opinion concurring in the judgment.

Sincerely,

HAB

Justice Stevens

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE HARRY A. BLACKMUN

March 16, 1983

Re: No. 81-1222 - United States v. Generix Drug Corp.

Dear John:

Please join me in your recirculation of March 16. I therefore am withdrawing my separate opinion that concurred in the judgment.

Sincerely,



Justice Stevens

cc: The Conference

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE LEWIS F. POWELL, JR.

March 1, 1983

81-1222 United States v. Generix Drug Corp.

Dear John:

Please join me.

Sincerely,



Justice Stevens

lfp/ss

cc: The Conference

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE WILLIAM H. REHNQUIST

March 2, 1983

Re: No. 81-1222 United States v. Generix Drug  
Corporation

Dear John:

Please join me.

Sincerely,

*WRM*

Justice Stevens

cc: The Conference

JPS  
Please see [unclear]  
[unclear]

To: The Chief Justice  
Justice Brennan  
Justice White  
Justice Marshall  
Justice Blackmun  
Justice Powell  
Justice Rehnquist  
Justice O'Connor

From: **Justice Stevens**

Circulated: MAR 1 '83

Recirculated: \_\_\_\_\_

1st DRAFT

**SUPREME COURT OF THE UNITED STATES**

No. 81-1222

**UNITED STATES, PETITIONER v. GENERIX DRUG CORPORATION, ET AL.**

**ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT**

[March —, 1983]

JUSTICE STEVENS delivered the opinion of the Court.

The question presented is whether the statutory prohibition against the marketing of a "new drug" without the prior approval of the Food and Drug Administration (FDA) applies to a generic drug product containing the same active ingredients as a pioneer drug product that has previously been approved. In statutory terms the issue is whether the term "drug" as used in the relevant sections of the Federal Food, Drug, and Cosmetic Act (Act), as amended, 21 U. S. C. §§ 301 *et seq.*, refers only to the active ingredient in a drug product or to the entire product. We hold that Congress intended the word to have the broader meaning.

I

The active ingredients in most prescription drugs constitute less than 10 percent of the product; inactive "excipients" (such as coatings, binders, and capsules) constitute the rest. The term "generic drug" is used to describe a product that contains the same active ingredients but not necessarily the same excipients as a so-called pioneer drug that is marketed under a brand name.<sup>1</sup> Respondent Generix is a distributor of generic drugs manufactured by other firms.

<sup>1</sup>Generic drugs, also called "copycat" or "me-too" drugs, are usually

*Join*

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To: The Chief Justice  
Justice Brennan  
Justice White  
Justice Marshall  
Justice Blackmun  
Justice Powell  
Justice Rehnquist  
Justice O'Connor

27. 3,7-8

From: **Justice Stevens**

Circulated: \_\_\_\_\_

Recirculated: **MAR 11 '83**

2nd DRAFT

**SUPREME COURT OF THE UNITED STATES**

No. 81-1222

UNITED STATES, PETITIONER *v.* GENERIX  
DRUG CORPORATION ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF  
APPEALS FOR THE ELEVENTH CIRCUIT

[March —, 1983]

JUSTICE STEVENS delivered the opinion of the Court.

The question presented is whether the statutory prohibition against the marketing of a "new drug" without the prior approval of the Food and Drug Administration (FDA) applies to a generic drug product containing the same active ingredients as a pioneer drug product that has previously been approved. In statutory terms the issue is whether the term "drug" as used in the relevant sections of the Federal Food, Drug, and Cosmetic Act (Act), as amended, 21 U. S. C. §§ 301 *et seq.*, refers only to the active ingredient in a drug product or to the entire product. We hold that Congress intended the word to have the broader meaning.

I

The active ingredients in most prescription drugs constitute less than 10% of the product; inactive "excipients" (such as coatings, binders, and capsules) constitute the rest. The term "generic drug" is used to describe a product that contains the same active ingredients but not necessarily the same excipients as a so-called pioneer drug that is marketed under a brand name.<sup>1</sup> Respondent Generix is a distributor of generic drugs manufactured by other firms.

<sup>1</sup>Generic drugs, also called "copycat" or "me-too" drugs, are usually

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE JOHN PAUL STEVENS

March 16, 1983

Re: 81-1222 - United States v. Generix Drug Corp.

Dear Harry:

Enclosed is the redraft I plan to circulate to the conference. I believe it may eliminate the area of disagreement between your opinion and the prior draft and therefore will be most interested in your reaction to it.

Respectfully,



Justice Blackmun

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE JOHN PAUL STEVENS

March 16, 1983

MEMORANDUM TO THE CONFERENCE

Re: 81-1222 - United States v. Generix  
Drug Corp.

The attached draft narrows our holding in order to avoid decision of the question that Harry discussed in his thoughtful separate concurrence. I am now persuaded that we do not need to decide in this case when, if ever, trivial differences (perhaps such as a different colored capsule) would prevent two drug products from being considered the same drug for statutory purposes.

Respectfully,



STYLISTIC CHANGES THROUGHOUT.  
SEE PAGES: 1, 2, 4, 6-8

To: The Chief Justice  
Justice Brennan  
Justice White  
Justice Marshall  
Justice Blackmun  
Justice Powell  
Justice Rehnquist  
Justice O'Connor

From: Justice Stevens

Circulated: \_\_\_\_\_

Recirculated: MAR 16 '83

3rd DRAFT

**SUPREME COURT OF THE UNITED STATES**

No. 81-1222

UNITED STATES, PETITIONER *v.* GENERIX  
DRUG CORPORATION ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF  
APPEALS FOR THE ELEVENTH CIRCUIT

[March —, 1983]

JUSTICE STEVENS delivered the opinion of the Court.

The question presented is whether the statutory prohibition against the marketing of a "new drug" without the prior approval of the Food and Drug Administration (FDA) requires the respondent to have approved new drug applications (NDAs) before it may market its generic drug products. In statutory terms, we are required to determine whether the term "drug" as used in the relevant sections of the Federal Food, Drug, and Cosmetic Act (Act), as amended, 21 U. S. C. §§ 301 *et seq.*, refers only to the active ingredient in a drug product or to the entire product. We hold that Congress intended the word to have the broader meaning.

I

The active ingredients in most prescription drugs constitute less than 10% of the product; inactive "excipients" (such as coatings, binders, and capsules) constitute the rest. The term "generic drug" is used to describe a product that contains the same active ingredients but not necessarily the same excipients as a so-called "pioneer drug" that is marketed under a brand name.<sup>1</sup> Respondent Generix is a distributor of generic drugs manufactured by other firms.

<sup>1</sup>Generic drugs, also called "copycat" or "me-too" drugs, are usually

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7/1/83

Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE JOHN PAUL STEVENS

8

March 22, 1983

MEMORANDUM TO THE CONFERENCE

Re: Case held for United States v. Generix Drug Corp., No. 81-1222

No. 81-2402, Performance Products, Inc. v. United States

Petitioner manufactures equidantin, a generic copy of an FDA-approved horse drug. The petitioner has never filed a new drug application for equidantin. Equidantin has the same active ingredient as the pioneer, but it has different excipients and the petitioner has never done any studies to see whether they are bioequivalent. The Government sought condemnation and seizure of the drug, much as it did in Generix. And, as in Generix, the petitioner defended on the ground that their product is not a "new animal drug" because it contains the same active ingredient as an approved drug. The district court ruled for the Government. It went on to note that, even if only the active ingredient were significant, equidantin would still be a new product: the active ingredient, although approved, was still not "generally recognized as safe and effective." CA8 affirmed.

The cert. petition presents the same issue as we decided in Generix--whether, regardless of bioavailability, a drug product is not a "new [animal] drug" simply because it contains the same active ingredient. It does not present the question reserved in Generix--under what circumstances, if any, two bioequivalent drugs are the same drug. Since CA8's decision is consistent with our own, I will vote to deny.

Respectfully,



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Supreme Court of the United States  
Washington, D. C. 20543

CHAMBERS OF  
JUSTICE SANDRA DAY O'CONNOR

March 1, 1983

No. 81-1222 U. S. v. Generix Drug Corp.

Dear John,

Please join me.

Sincerely,



Justice Stevens

Copies to the Conference