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CONGRESSIONAL RECORD
PROCEEDINGS AND DEBATES OF THE 98TH CONGRESS

SENATE

| BILL | DATE | PAGE(S) |
|---|---|---|
| S.Con.Res.141 | SEP 12 '84 (113) | S11096 |

ACTION: *Correction of Enrollment:* Senate agreed to S. Con. Res. 141, making technical corrections in the enrollment of S. 1538, Drug Price Competition and Patent Term Restoration Act.

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## FEDERAL FOOD, DRUG, AND COSMETIC ACT AMENDMENTS

Mr. STEVENS. Mr. President, I send to the desk a concurrent resolution on behalf of Senator HATCH and ask for its immediate consideration.

The PRESIDING OFFICER. The concurrent resolution will be stated.

The assistant legislative clerk read as follows:

A concurrent resolution (S. Con. Res. 141) to correct technical errors in the enrollment of S. 1538.

The PRESIDING OFFICER. Is there objection to the present consideration of the concurrent resolution?

There being no objection, the Senate proceeded to consider the concurrent resolution.

Mr. HATCH. Mr. President, when S. 1538 came over from the House, it contained an error in an addition made in the House to modify the so-called patent certification provision. The House inserted the phrase "if the court decides that such patent is not invalid or not infringed." The intent of the language is to clarify that the ANDA in a patent challenge situation, where the judge has issued a preliminary injunction, is to be made effective when the court issues a decision that a patent is invalid or not infringed. The presence of the double negative "not infringed" in the House language is an error, and this concurrent resolution simply enables that error to be corrected. Without having to refer the entire bill, S. 1538, back to the House for another vote and more needless delay.

The concurrent resolution was agreed to, as follows:

*Resolved by the Senate (the House of Representatives concurring),* That, in the enrollment of the bill (S. 1538) to amend the Federal Food, Drug, and Cosmetic Act as added by to revise the procedures for new drug applications, to amend title 35, United States Code, to authorize the extension of the patents for certain regulated products, and for other purposes, the Secretary of the Senate shall make the following changes. In sections 505(j)(4)(B)(iii)(III) and 505(c)(3)(C)(ii) of the Federal Food, Drug, and Cosmetic Act as added by sections 101 and 103(b) of the bill, respectively, strike out "not invalid" and insert in lieu thereof "invalid".

Mr. STEVENS. Mr. President, I move to reconsider the vote by which the concurrent resolution was agreed to.

Mr. BYRD. I move to lay that motion on the table.

The motion to lay on the table was agreed to.