

(2) EFFECTIVE DATE.—The requirement of licensure under section 511 of the Federal Food, Drug, and Cosmetic Act (as added by this section) shall take effect on the date determined by the Secretary of Health and Human Services but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

(e) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended by adding at the end the following:

“(g) Notwithstanding subsection (a), any person who knowingly violates paragraph (1), (2), (3), or (4) of section 301(hh) shall be imprisoned for not more than 10 years or fined in accordance with title 18, United States Code, or both.”.

SA 1058. Mr. DEMINT (for himself, Mr. COBURN, and Mr. MARTINEZ) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____ SENSE OF THE SENATE REGARDING CERTAIN PATENT INFRINGEMENTS.

(a) FINDINGS.—The Senate makes the following findings:

(1) The value of American innovation in developing life-saving prescription drugs saves millions of lives around the world each year.

(2) The protection of intellectual property is vital to the continued development of new and life-saving drugs and future growth of the United States economy.

(3) In order to maintain the global competitiveness of the United States, the United States Trade Representative's Office of Intellectual Property and Innovation develops and implements trade policy in support of vital American innovations, including innovation in the pharmaceutical and medical technology industries.

(4) The United States Trade Representative also provides trade policy leadership and expertise across the full range of interagency initiatives to enhance protection and enforcement of intellectual property rights.

(5) When other countries do not respect the intellectual property of American drug companies, all patients suffer because of diminished incentives to develop new life-saving medications and the American economy is unfairly harmed.

(6) Strong intellectual property protection, including patent, copyright, trademark, and data protection plays an integral role in fostering economic growth and development and ensuring patient access to the most effective medicines around the world.

(7) Certain countries have engaged in unfair price manipulation and abuse of compulsory licensing. This results in Americans bearing the majority of research and development costs for the world, undermines the value of existing United States pharmaceutical patents and could impede access to important therapies.

(8) There is a growing global threat of counterfeit medicines and increased need for the United States Trade Representative and other United States agencies to use available trade policy measures to strengthen laws and enforcement abroad to prevent harm to United States patients and patients around the world.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that—

(1) the United States Trade Representative should use all the tools at the disposal of the

Trade Representative to deal with violations of intellectual property rights, including—

(A) bilateral engagement with United States trading partners;

(B) transparency of the annual “Special 301” review and reviews of compliance with the intellectual property requirements of countries with respect to which the United States grants trade preferences;

(C) negotiation of intellectual property provisions as part of bilateral and regional trade agreements; and

(D) multilateral engagement through the World Trade Organization (WTO); and

(2) the United States Trade Representative should develop and implement a strategic plan to address the problem of countries that infringe upon American pharmaceutical intellectual property rights and the problem of countries that engage in price manipulation.

SA 1059. Mr. SESSIONS (for himself, Mrs. LINCOLN, Mr. COCHRAN, Mr. PRYOR, Mr. LOTT, and Mr. SHELBY) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____ ENHANCED AQUACULTURE AND SEAFOOD INSPECTION.

(a) FINDINGS.—Congress finds the following:

(1) In 2007, there has been an overwhelming increase in the volume of aquaculture and seafood that has been found to contain substances that are not approved for use in food in the United States.

(2) As of May 2007, inspection programs are not able to satisfactorily accomplish the goals of ensuring the food safety of the United States.

(3) To protect the health and safety of consumers in the United States, the ability of the Secretary of Health and Human Services to perform inspection functions must be enhanced.

(b) HEIGHTENED INSPECTIONS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the “Secretary”) shall, by regulation, enhance, as necessary, the inspection regime of the Food and Drug Administration for aquaculture and seafood, consistent with obligations of the United States under international agreements and United States law.

(2) CONTENT.—The Secretary shall ensure that the regulations promulgated under paragraph (1) to enhance the inspection regime—

(A) ensure that aquaculture and seafood products are not contaminated with substances that are not approved for use in food in the United States;

(B) include the authority to refuse imports of such products from a foreign facility if a requested inspection of the foreign facility is refused or unnecessarily delayed;

(C) take into account whether the United States has a cooperative agreement regarding aquaculture and seafood inspection; and

(D) provide for an assessment of the risk associated with particular contaminants.

(c) REPORT TO CONGRESS.—Not later than 90 days after the date of enactment of this Act, the Secretary shall submit to Congress a report that describes—

(1) the specifics of the aquaculture and seafood inspection program; and

(2) the feasibility of developing a traceability system for all catfish and seafood products, both domestic and imported,

for the purpose of identifying the processing plant of origin of such products.

(d) PARTNERSHIPS WITH STATES.—Upon the request by any State, the Secretary may enter into partnership agreements, as soon as practicable after the request is made, to implement inspection programs regarding the importation of aquaculture and seafood.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

SA 1060. Mr. HATCH (for himself and Mr. KENNEDY) submitted an amendment intended to be proposed by him to the bill S. 1082, to amend the Federal Food, Drug, and Cosmetic Act to reauthorize and amend the prescription drug user fee provisions, and for other purposes; which was ordered to lie on the table; as follows:

At the appropriate place, insert the following:

SEC. ____ FOOD AND DRUG ADMINISTRATION FUNDING SUBMISSION.

Subchapter A of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371 et seq.), as amended by this Act, is amended by adding at the end the following:

“SEC. 714. FOOD AND DRUG ADMINISTRATION FUNDING SUBMISSION.

“For each of fiscal years 2009 through 2013, the Commissioner of Food and Drugs shall prepare and submit, directly to the President for review and transmittal to Congress, an annual Food and Drug Administration funding submission estimate (including the number and type of personnel needs for the Food and Drug Administration), after reasonable opportunity for comment (but without change) by the Secretary.”.

NOTICE OF HEARING

SUBCOMMITTEE ON PUBLIC LANDS AND FORESTS

Mr. BINGAMAN. Mr. President, I would like to announce for the information of the Senate and the public that a hearing has been scheduled before the Subcommittee on Public Lands and Forests of the Committee on Energy and Natural Resources.

The hearing will be held on Wednesday, May 30, at 12 p.m. in the Medford City Council Chambers at 411 West 8th Street in Medford, Oregon.

The purpose of the hearing is to receive testimony on the impacts of the Chinese hardwood plywood trade on the National Forest System and other public lands, and the communities that depend on them.

Because of the limited time available for the hearing, witnesses may testify by invitation only. However, those wishing to submit written testimony for the hearing record should send it to the Committee on Energy and Natural Resources, United States Senate, Washington, DC 20510-6150, or by e-mail to rachel.pasternack@energy.senate.gov.

For further information, please contact Scott Miller at (202) 224-5488 or Rachel Pasternack at (202) 224-0883.

UNANIMOUS-CONSENT AGREEMENT—EXECUTIVE CALENDAR

Mr. BROWN. Mr. President, I ask unanimous consent that at 11:50 tomorrow, the Senate proceed to executive