

Caterpillar Inc.
Eastman Kodak Company
General Motors Corporation

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0417/Proposed Rule: Applications for FDA Approval to
Market a New Drug

Dear Sir or Madam:

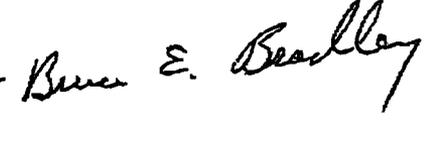
On behalf Caterpillar Inc., Eastman Kodak Company, and General Motors Corporation, we are pleased to submit the enclosed joint comment to the FDA's above-referenced Proposed Rule. As leading innovators in our respective industries and providers of health care coverage to nearly 1.5 million Americans, we believe we bring a voice of moderation to this process, aiming to help reach the intended balance between innovation and timely access to therapeutic drugs.

Thank you for the opportunity to submit these comments. We look forward to working with the FDA throughout this regulatory process. If you have any questions or would like to discuss our comment further, then please call either Edward Kaleta of Caterpillar Inc. at (202) 466-0671, Amy Plaster of Eastman Kodak Company at (202) 857-3465, or Annette Guarisco of General Motors Corporation at (202) 775-5080.

Respectfully submitted,



Greg Folley
Director of Compensation
And Benefits
Caterpillar Inc



Robert Berman
Director, Human Resources
Vice President
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02N-0417

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JOINT COMMENTS BY CATERPILLAR INC., EASTMAN KODAK COMPANY, AND
GENERAL MOTORS CORPORATION

Re: Docket No. 02N-0417/Proposed Rule: Applications for FDA Approval to Market a New Drug

Executive Summary
Supporting the Proposed Rule With Modifications: A Fair Balance

Who We Are

- We are Caterpillar Inc., Eastman Kodak Company, and General Motors Corporation.
- We provide health care coverage to nearly 1.5 million Americans.
- Collectively we spend \$5.4 billion per year for health care, more than \$1.5 billion of which, or 28%, is for prescription drugs.
- As leading innovators in our respective industries and providers of health care, we believe we bring a voice of moderation to this process, aiming to help reach the intended balance between innovation and timely access.

Patent Declaration Issues

- The FDA should require brand name companies to re-certify their patents currently on the Orange Book list, utilizing the patent declaration with our recommended modifications.
- The FDA needs to develop the expertise and exercise the appropriate oversight of the patent declaration process to ensure only eligible patents are listed in the Orange Book, both on a prospective and retrospective basis.
- A statement should be added to the patent declaration that no patents ineligible for listing are or will be declared for listing.
- A statement should be added to the patent declaration requiring identification of published pending patent applications, if expected to be eligible for listing, and intent to list or not to list.
- The FDA should require a certified signature with false statement acknowledgement.

30 Month Stay Issue

- We support the agency's revised interpretation that the Hatch–Waxman Amendments permit only one 30-month automatic stay.
- New delay tactics could result, however, slowing access to affordable drugs.

Orange Book Listing Issue

- Add patents for uses not approved by the FDA, and certain patents not requiring clinical trial data for FDA approval, to the exclusions list.

Introduction

As the providers of health care coverage to a total of nearly 1.5 million Americans at an annual cost of \$5.4 billion, the Eastman Kodak Company, General Motors Corporation, and Caterpillar Inc. appreciate the opportunity to comment on the U.S. Food and Drug Administration's (FDA) Proposed Rule intended to improve the availability of, and patient access to, therapeutic drugs. More than 28% of our total expenditures or \$1.5 billion are spent on prescription drugs each year. This percentage has been and will continue to rise unless the Federal Government steps in to make both administrative and legislative changes to this vitally important segment of our health care delivery system. As self-insured employers, we provide quality health care coverage to our beneficiaries, but must find ways to manage this very significant and expensive component of our health care costs. We know that avoidable delays in bringing generic drugs to market undermine our ability to provide our beneficiaries access to affordable drugs.

It must be recognized that the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Amendments"¹) and implementing regulations are nearly 20 years old. As is often the intent of legislation, these Amendments have modified the behavior of both the brand name and generic drug manufacturers, most of which has been for the benefit of the public. As noted in the July 2002 FTC Report, however, stakeholder conduct during the past few years has undermined the intent of the Hatch-Waxman Amendments and its implementing regulations.² We support changes to the system that will achieve a balance between innovation and access, originally gained, but recently lost. We therefore applaud the FDA's administrative effort, which we view as an important, but incremental, first step. While we recognize the agency is limited in what it can accomplish through the rule making process, we believe a bit more can and should be done through this venue. We also appreciate that certain changes likely will require legislative action and encourage the FDA's support in this regard.

Just like the brand name pharmaceutical companies, we too are innovators in our respective fields. We understand the capital investment necessary to innovate and bring a quality product to market, and the need to run a successful business. As such, we do not advocate for the diminishment of patent protection afforded by federal law, particularly that provided for by the Hatch-Waxman Amendments. As providers of health care coverage, however, we do support the FDA's revised interpretation of the Hatch-Waxman Amendments, which is intended to promote patient access to drugs by making them more affordable. If we are to compete successfully in the global marketplace, then drug costs must be brought under

¹ 21 U.S.C. § 355 *et seq.* (2001).

² *See, Generic Drug Entry Prior to Patent Expiration: An FTC Study*, F.T.C. (2002).

control. Sharing the Administration's goal of striking the proper balance between innovation and access, we support the FDA's Proposed Rule, and share with the agency the following suggested modifications.

Discussion

Proposed § 314.53(c)(2)(i) – What Does the Patent Declaration Say?

There are three issues for the FDA to consider when it modifies the patent declaration: the content of the declaration; the FDA's remedy if the declaration causes an ineligible patent to be listed in the Approved Drug Products With Therapeutic Equivalence Evaluations list (the "Orange Book"); and the applicant's penalty if the declaration causes an ineligible patent to be listed in the Orange Book. The very conduct by some brand name pharmaceutical companies,³ which prompted the FDA to issue this Proposed Rule, suggests that for any of these proposed reforms to have meaning, there must be remedies available and penalties to be meted out when a patent declaration is incomplete or false.

The FDA has taken the position that it continues to "lack the expertise, resources, and legal authority to examine patent issues."⁴ To rectify these shortcomings, the agency is proposing to "ask NDA applicants and NDA holders to provide more patent information to help ensure that only appropriate patents are listed." *Id.* While we agree that obtaining more information is an important step, government oversight is necessary. The process as designed presumes accurate patents declarations will be made, thus not requiring oversight. As the FTC Report makes clear, unfortunately, we literally cannot afford to make this presumption. Absent the FDA's ability to independently judge and take action on the additional information provided by the patent holders, we are concerned that the regulations as modified would not contain drug costs and therefore not improve patient access to affordable drugs.

While we believe the additional declaration-related modifications discussed below should discourage brand name pharmaceutical companies from declaring ineligible patents for Orange Book listing, we believe that the FDA must have the capacity to advise companies to remove ineligible patents from the Orange Book listing or delist them itself. The FDA must also have the ability to advise companies not to list ineligible patents in their declarations or not list them itself in the first instance.

³ *See, Generic Drug Entry Prior to Patent Expiration: An FTC Study*, F.T.C. (2002).

⁴ Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 67 Fed. Reg. 65,448, 65,453 (proposed Oct. 24, 2002) (to be codified at 21 C.F.R. pt. 314).

We recognize that many stakeholders believe legislation is necessary to provide the FDA with delisting authority. This may in fact be the case, and it is an issue we will continue to evaluate. In the meantime, however, we believe there are administrative options the FDA should explore to establish an effective oversight function. For example, the FDA, exercising its hiring authority, should identify and retain the services of qualified individuals for the limited purpose of examining patent declarations for Orange Book listing purposes. The professionals could advise either the declarants or the FDA on the appropriateness of listing the patents declared. This could be done retrospectively through recertifications of patents currently on the Orange Book listing, as well as prospectively for certifications to be made in the future. One possible resource for the FDA to explore could be the U.S. Patent and Trademark Office's (PTO) Legal Department. It is our understanding that this office currently works with the FDA on patent term extension issues related to regulatory delay. If, after assessing all its options, the FDA does not believe appropriate expertise is available, then it should consider investing the resources necessary to develop the expertise. While we are sensitive to the fact that the FDA currently may not have the resources to oversee this process, we encourage it to exercise its administrative authority to reorder its priorities to fund such an activity or to seek the necessary additional funds from Congress.

We certainly support the FDA's efforts to obtain more information from NDA applicants and NDA holders through the patent declaration process. To make this process more effective and efficient, we would suggest the declaration be modified to reflect more completely the § 314.53(b) "do's and don'ts." We recommend, therefore, that the declaration be modified to elicit an express statement that no patents ineligible for listing are or will be declared for listing. In addition, we would recommend that the declaration also require applicants to identify published pending patent applications, and state whether the patents are expected to be eligible for listing, and whether they intend to declare them for listing upon issuance of the patent. Given pending patent applications are published by the PTO 18 months after filing, we do not believe there should be any impediments to include this in the declaration. If a patent application is pending but unpublished at the time of the original patent declaration, then the applicant should be required to update its declaration when the PTO publishes the pending patent application.

Finally, it is critically important that applicants making a patent declaration for Orange Book listing purposes understand fully these declarations must be complete, accurate, and truthful. There are numerous contexts throughout the Federal Government in which declarations made to a federal agency are certified with an express acknowledgement regarding the potential penalties for providing information to the federal government that is either incomplete, inaccurate, or false. To encourage full compliance and to be clear that the federal government can exercise its enforcement authority under current law, we would propose that the

patent declaration be signed as a certified statement with a standard acknowledgement clause. Although the FDA's *Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use* (Form 356h [9/02]) contains a warning above the signature block about the applicant making willfully false statements, we would recommend it, and other patent declarations to the FDA, be modified to state the following:

I hereby certify that the data and information in this submission have been reviewed and, to the best of my knowledge are certified to be complete, true, and accurate. Further, I understand that a willfully false statement is a criminal offense under 18 U.S. Code, title 18, § 1001.

Proposed §§ 314.94(a) and 314.52(a) – How Many Times Can an Application's Approval Date be Delayed for a 30-Month Period?

As innovators and holders of more than 15,000 active patents collectively among our three companies, we support the goal of the brand name innovators in the pharmaceutical industry to obtain the maximum available patent protection our patent laws provide. Keeping in mind the importance of striking the proper balance between innovation and access, we also support the FDA's conclusion that multiple 30-month stays were not intended by the Hatch–Waxman Amendments. We agree with the agency that only one 30-month stay was intended and therefore that its regulations should be modified to reflect its revised and correct interpretation.

This approach is the correct one to the extent it reduces drug costs and improves patient access sooner rather than later by virtue of removing a company's ability to delay market entry through multiple 30-month stays. One automatic 30-month stay may modify brand name manufacturers' behavior in several ways, some of which should facilitate the availability of affordable drugs, and some of which may cause additional delays the FDA intends to avoid. For example, limiting brand name manufacturers to one 30-month stay should also discourage them from listing ineligible patents since doing so will not create more automatic stay opportunities. This would be a positive result since the current system benefits both the brand name and generic drug manufacturers, all of which is to the detriment of the consumer, when ineligible patents are listed in the Orange Book. Current FDA interpretation of the law permits the brand name manufacturers to create multiple 30-month stay opportunities, and generic manufacturers to receive 180 day exclusivity at the conclusion of each successful challenge, even when the challenge is to a patent inappropriately listed. While the Proposed Rule does not address the 180 day generic exclusivity requirement, we invite the FDA to consider administrative measures to stop the abuses highlighted by the July 2002 FTC Report.⁵

⁵ *See, Generic Drug Entry Prior to Patent Expiration: An FTC Study*, F.T.C. (2002).

We also understand, however, that the availability of only one automatic 30-month stay may encourage brand name manufacturers to risk waiting until the last possible moment before the generic competitor can market and sell its drug to file an infringement lawsuit and seek an injunction. If successful, this tactic would produce the unintended consequence of further delaying access to affordable drugs. The lack of certainty created regarding patent dispute resolution may discourage a generic drug manufacturer from entering the field at all. Recognizing that the FDA is limited in what it can do to address these exclusivity protections through regulation, we will continue to evaluate these issues in search of the most effective and fair solution for the brand name drug manufacturers, the generic drug manufacturers, the purchasers, and the consumers of their products.

Proposed § 314.53(b) – What Patents Must Be Listed in the Orange Book?

We support the proposed modifications to § 314.53(b). The agency has identified the three major loopholes in need of closing: patents claiming packaging; patents claiming metabolites; and patents claiming intermediaries. The agency's additional clarifications regarding patents that claim a drug substance, drug product, or method of use should also help keep ineligible patents out of the Orange Book.

There are additional exclusions, however, that we would recommend the FDA consider. Consistent with the agency's interpretation of the Hatch–Waxman Amendments that the patent "must claim the approved drug product or a method of using the approved drug product,"⁶ we believe the Final Rule should expressly exclude from Orange Book listing eligibility patents obtained for uses not approved by the FDA. It is not uncommon for physicians to discover "off label" or unapproved uses of drugs to treat patients. By definition, these "off label" or unapproved uses do not undergo the scrutiny of the FDA approval process and thus the brand name manufacturers need not invest the time and resources to conduct the clinical trials necessary for FDA approval. Therefore, if a brand name manufacturer makes the judgment not to obtain FDA approval for an unapproved use, then when it obtains a patent on that unapproved use, it should not be able to benefit from an automatic 30-month stay by listing the patent in the Orange Book.

We would also recommend certain polymorph patents and method of use patents be excluded from Orange Book listing. More specifically, Orange Book listing should not be an option in those instances when the polymorph drug or the new method of use does not require clinical trial data for FDA approval. We

⁶ Applications for FDA Approval to Market a New Drug: Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed, 67 Fed. Reg. 65,448, 65,449 (proposed Oct. 24, 2002) (to be codified at 21 C.F.R. pt. 314).

recognize that some, but not all, polymorph drugs or new methods of use for approved drugs require clinical trial data for FDA approval. For those on which the FDA requires clinical trial data, given the time and investment brand name manufacturers make in those instances, they should be permitted to list the polymorph patents and method of use patents in the Orange Book.⁷

Conclusion

The Eastman Kodak Company, General Motors Corporation, and Caterpillar Inc. applaud the FDA's interest in improving the implementation of the Hatch-Waxman Amendments and appreciate the difficult task it faces as many reforms likely will require legislative action. As innovators and providers of health care coverage, our comments are intended to help the FDA refine its proposed regulations to better achieve the proper balance between innovation and access sought by the Hatch-Waxman Amendments nearly 20 years ago.

We provide quality health care coverage to our beneficiaries, but must find ways to manage this very significant and expensive component of our health care costs. Representing more than 28 cents for every dollar we spend on health care coverage, the growing expense of drugs must be reversed. For us, remaining competitive as innovators in the global marketplace means containing our health care costs, particularly drug costs through accelerated competition and improved access. Our comments are intended to improve the likelihood of this outcome. Thank you again for the opportunity to comment and we look forward to working with the FDA throughout this regulatory process.

⁷ Please note that these exclusions are distinct from the unapproved use exclusion in that these patents link to FDA approved uses.