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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852
e-Comments to http://www.fda.gov/dockets/ecomments

Re: Docket No. 02N-0417: Proposed Rule -- 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

Introduction

These comments are submitted by Consumers Union (CU)[1] and the Consumer Federation of America (CFA)[2] regarding the Proposed Rule in the above docket (Proposed Rule). The proposed rule would amend U.S. Food and Drug Administration (FDA) patent listing requirements in order to address

[1]Consumers Union is a nonprofit membership organization chartered in 1936 under the laws of the State of New York to provide consumers with information, education and counsel about good, services, health, and personal finance; and to initiate and cooperate with individual and group efforts to maintain and enhance the quality of life for consumers. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and from noncommercial contributions, grants and fees. In addition to reports on Consumers Union's own product testing, *Consumer Reports* with approximately 4.5 million paid circulation, regularly, carries articles on health, product safety, marketplace economics and legislative, judicial and regulatory actions which affect consumer welfare. Consumers Union's publications carry no advertising and receive no commercial support.

[2] The Consumer Federation of America is a non-profit association of 300 organizations that, since 1968, has sought to advance the consumer interest through advocacy and education. For the last twenty years,

02N-0417 C 32

anticompetitive tactics used by brand name prescription drug companies to stall the introduction of lower priced generic drugs.

Part of FDA's mission is to ensure the safety and efficacy of prescription drugs. However, existing drug therapies are of little value if consumers cannot afford them. Currently, the number of uninsured people is on the rise -- the number of Americans without health uninsured rose by 1.4 million to 41.1 million in 2001.[3] Consequently, ongoing and repeated delays of consumer access to lower cost generic drugs thwart the intent of Hatch-Waxman legislation -- and must be addressed.

These comments address three major changes that the Proposed Rule would make to existing FDA regulations: (1) clarifying the types of patents that must and must not be listed; (2) revising the patent declaration that NDA applicants must file with FDA; and (3) allowing only one 30-month stay in the approval date of each ANDA.[4]

CU and CFA applaud the Agency for attempting to focus on these issues. However we believe that this regulatory approach has significant limitations, and that the specific proposals contain serious flaws. In sum, we believe the proposed rule is unlikely to significantly reduce the anticompetitive tactics that have been used to delay market entry of generic drugs, and may actually

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CFA has regularly offered comments on regulatory proposals and legislation related to drug pricing and patents.

[3] U.S. Census Bureau findings cited in The New York Times, September 30, 2002.

[4] (67 Fed. Reg. 65,448, (October 24, 2002), at 65,448).

encourage these tactics in some cases, by requiring the listing of new categories of patents. The Agency must seek additional statutory authority in order to address these problems in a legally sustainable way that will not be vulnerable to legal attacks to the Agency's authority.

In July of this year the Federal Trade Commission (FTC) studied the existing FDA drug approval system, as well as the improper delays caused by the exploitation of loopholes in the law. The Commission issued recommendations for legislative solutions to the anticompetitive activities that deny consumers access to lower-priced generic drugs. The FTC specifically recommended limiting companies that challenge generic product entry (claiming patent infringement) to only one 30-month stay. This restriction would prevent abusive tactics used by some companies to improperly obtain multiple 30-month stays against competing generic drug products. In addition, the FTC recommended that Congress address the 180-day exclusivity provision, in order to prevent improper delay of the approval of subsequent generic drug products.[5]

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[5] See "Generic Drug Entry Prior to Patent Expiration: An FTC Study," Federal Trade Commission, July 2002 (FTC Report). FDA does not address the 180-day exclusivity provision in its Proposed Rule. We support the FTC's recommendation that Congress pass a legislative solution, in the form of the "Drug Competition Act," introduced by Senator Leahy (D-VT) in the 107th Congress. As described by the FTC, it:

> would require that if a brand-name company and a generic applicant enter into an agreement that relates in any way to the 180-day exclusivity or which concerns the manufacture, marketing, or sale of either the brand name drug or its generic equivalent, then both companies must file a copy of the agreement (or a complete written summary of any oral agreement), along with copies of any other related agreements, with the Commission and the Department of Justice. FTC Report at viii.

Clarification of Types of Patents that Cannot Properly be Listed

Improperly, and often fraudulently, listed patents have proven to be an unfair barrier to entry for generic drug company products. The listing of patents that do not qualify for entry in the "Approved Drug Products with Therapeutic Equivalence Evaluations," (Orange Book) too often have served as ammunition for brand name drug companies to prevent generic drug companies from bringing their products to market.[6] We support the Agency's efforts to address the types of patents that must not be listed in the Orange Book, such as for product packaging or containers, metabolites, and intermediates.[7]

Requirements for Additional Details in Patent Declarations for NDA Applicants

We support the Agency's proposal to require a more detailed patent declaration for patents to be listed in the Orange Book. The Agency's proposal would require NDA applicants to more thoroughly describe the patents certified to claim a drug formulation, composition, and/or method of use. We believe that this requirement will help decrease the number of improper patent listings. However, we strongly believe that the most significant measure the FDA should take to minimize improper listings is to develop a procedure to review listings in the Orange Book.

[6]FTC Report at iii.

Patents that Must be Listed in the Orange Book

We do not support the Agency's proposal to require additional patents to be listed in the Orange Book. This rulemaking became necessary due to the past abuses of existing Hatch-Waxman law. We oppose the expansion of the type of patents that may be listed in the Orange Book, and believe that such an expansion will provide additional opportunity for brand name companies to game the Orange Book listing system. The specific types of patents (for patent-by-process and polymorphs) that are considered in the Proposed Rule should not be considered to be proper listings.[8]

Process patents may not be listed in the Orange Book. In its Report, the FTC specifically highlighted the similarity of product-by-process patents to process patents, and stated that "product-by-process claims are arguably similar to process patents than are product patents. . . ." In addition, the FTC states that "the scope of patent coverage afforded by a product-by process patent for small-molecule pharmaceuticals typically is identical to that afforded by the corresponding process patent."[9] As stated by the FTC in its Report, product-by-process patents may be virtually indistinguishable from unlistable process patents. Although the FTC recommended that the Agency clarify the differences between unlistable process patents and patent-by-process,[10] it is unlikely that the

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[7] FDA Proposed Rule at 65451-52.
[8] See FDA Proposed Rule at 65452-53.

[9] FTC Report at A-43.
[10] FTC Report at A-44.

Commission intended for FDA to simply allow the listing of all patent-by-process patents. We believe that FDA should not expand the scope of listable patents to include patent-by-process patents because they do not fall within the three current acceptable types of patents (drug substance, drug product, and method of use)[11], and given the similarity and to unlistable process patents, such an expansion will likely subject to abuse, harmful to consumers.

In its Proposed Rule, the FDA also seeks to require the listing of polymorph patents. This proposal appears to be an inadvisable blending of patent and FDA bioequivalence concepts. As cited by the FTC in its Report:

> Listable patents are those that "claim" the approved drug product (a concept based on patent principles), and not every patent that a bioequivalent product [has] might infringe. The listing analysis is rooted in patent concepts, and the ability of two polymorphs to form bioequivalent products is not decisive to that analysis. If the ability of to polymorphs to form bioequivalent products made them the "same" for patent purposes (as opposed to FDA purposes), the brand-name company could never obtain the later polymorph patent in the first place because the earlier, approved polymorph would invalidate it.[12]

We oppose this requirement for similar reasons to the inclusion of product-by-process patents. We are concerned that it is, and will lead to additional abuse of the patent listing system.

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[11] See 21 C.F.R. §314.53 [CHECK]
[12] FTC Report at A-41.

Proposed Limitation to One 30-Month Stay Per ANDA

Brand-name drug companies currently exploit loopholes in the Drug Price Competition and Patent Term Restoration Act,[13] in order to bring unfounded patent infringement challenges to Abbreviated New Drug Applications (ANDAs), and prevent the entry of generic drugs for 30months. Brand-name companies have used these tactics to bring about multiple 30-month stays -- enabling them to continue their monopoly prices far beyond what the law intended.

Generally, we believe that the 30-month stay is unjustified and should be eliminated through a legislative amendment to Hatch-Waxman. We believe that, regardless of whether the 30-month stay is eliminated, any solution must eliminate the current "one way street" of legal remedies for the resolution of patent infringement disputes that tilt heavily to the advantage of brand manufacturers.

Currently, a brand name company can stay approval of an ANDA, regardless of the merits of its patent infringement challenge to a generic drug company's application. In its report, the FTC revealed that Courts that have decided disputes relating to late-listed patents (used by brand name companies as a basis for challenges to generic entry) have found a majority (over 70%) of the patent infringement claims to be invalid.[14]

[13]Pub. L. 98-417, 98 Stat. 1584 (1984), (Hatch-Waxman).
[14]FTC Report at 20.

A generic drug company faces potential treble damages if it brings a generic drug product to market and ultimately is found to have infringed upon the patent at issue. Despite the risks of entering the market under a cloud of patent infringement claims, generic drug companies have no mechanism to challenge an improper patent listing in the Orange Book—and no forum in which offer such a challenge.

The Agency's proposed rule would allow only one 30-month stay. We believe that the limitation of one 30-month stay per ANDA will be ineffective, at best. The Proposed Rule lacks: (1) an enforcement mechanism; (2) any disincentive for brand name companies to refrain from improper filing patents or filing late-listed patents; and (3) any mechanism to require the resolution of patent infringement disputes in a timely manner.

Currently, and under the Proposed Rule, if a generic drug company files a Paragraph IV certification and notifies the brand-name company (NDA holder), and the brand-name company sues the ANDA applicant for patent infringement, the FDA may not approve the ANDA for 30 months, or until resolution of the matter by a court. However, under the Proposed Rule, if a brand name company files an additional patent after an ANDA has been filed, but before approval, the generic applicant is not required to file an additional Paragraph IV certification under Section 505(j) of the Federal Food Drug and Cosmetic Act (FFDCA), 21 U.S.C 505(j)(5)(B)(iii), and the generic applicant need not give additional notice to the NDA holder. However, no 45-day clock will run, and the

NDA holder need not bring suit in a timely manner. Exacerbating the situation is the fact that the generic applicant likely will be denied the opportunity to seek a declaratory judgment under the same Section of the FFDCA.[15]

We believe that the FDA should use its existing authority, and where necessary seek additional authority, to monitor, review and enforce its patent listing requirements for the Orange Book. It is only in this way that the pubic and competitors that try to legitimately enter the market can be assured that patents are appropriately listed. We also believe that NDA holders should be restricted from listing patents in the Orange Book other than at or before the time of an initial NDA filing. The NDA applicant should be well aware of all relevant patents at the time of filing of a NDA application.

In sum, in light of (1) the unwillingness or inability of FDA to review patent listings for appropriateness; (2) the lack of requirement for companies to list all patents within a short time of initial NDA approval; (3) the additional patents that will be listed in the Orange Book; and (4) the absence of a mechanism in law or regulation, for a generic drug company to challenge a late-listed patents, we question the ability of this Proposed Rule, if promulgated as a Final Rule, to provide the certainty needed by generic drug companies prior to entering the market. As such, we do not believe that this proposed provision will serve to speed lower-cost generic drugs to consumers, and strongly urge the Agency to

[15] Id.

seek additional ways to ensure and enforce proper patent listings, and encourage patent disputes to be resolved in an expeditious manner.

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Respectfully Submitted,

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