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Food and Drug Administration
5630 Fishers Lane, Room 1061
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**Comments of Johnson & Johnson
on
FDA's 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"
[Docket No. 02N-0417]**

Johnson & Johnson appreciates the opportunity to submit these comments in response to the proposed rule published by the Food and Drug Administration ("FDA") on October 24, 2002, regarding the agency's implementation of certain provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments").¹ Johnson & Johnson the world's most comprehensive and broadly based manufacturer of health care products for the consumer, pharmaceutical, medical device and diagnostics markets.

Johnson & Johnson wishes to express, through these comments, its agreement with the comments of the Pharmaceutical Research and Manufacturers of America ("PhRMA") and, in particular, to emphasize and augment PhRMA's comments concerning the proposed changes to (1) the 30-month stay rule; (2) the content of Paragraph IV certification notices; and (3) patent listing declaration requirements.² Johnson & Johnson urges FDA to be mindful of the importance of maintaining the balance of competing interests and the careful compromise that led to the enactment of the Hatch-Waxman Amendments.

¹ 67 Fed. Reg. 65448 (Oct. 24, 2002).

² In offering these comments on the proposed rule, Johnson & Johnson takes no position on the merits of the statutory interpretation upon which the Agency relies to support this rulemaking.

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I. FDA's proposed rule creates an unintended loophole that could eliminate the opportunity to obtain even a single 30-month stay.

The Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act") provides that a party submitting an abbreviated new drug application ("ANDA") or an application under Section 505(b)(2) of the Act must give notice to new drug application ("NDA") and patent holders whenever the ANDA or 505(b)(2) application is "amended to include" a paragraph IV certification. FDCA §§ 505(b)(3)(C), 505(j)(2)(B)(iii). Receipt of this notice begins a 45-day review period. If the patent holder files a patent infringement challenge by the end of the period, the Act imposes a stay of up to 30 months on FDA approval of the generic drug application.

FDA seeks to eliminate the possibility that an NDA holder might be able to obtain more than one 30-month stay by listing additional patents after an ANDA or 505(b)(2) with a Paragraph IV certification has been filed. The focus of the agency's concern is the possibility that the NDA holder can somehow game the system by filing additional patents after the filing of the ANDA or 505(b)(2) application but before the expiration of the initially listed patents. No provision of the FDCA prohibits multiple stays for a particular product. Moreover, FDA can point to only a literal handful of cases where there has been more than one 30-month stay out of the thousands of generic drug applications processed by the agency since the enactment of the Hatch-Waxman Amendments. Thus, Johnson & Johnson questions the need for FDA's proposal in the first place.

Nonetheless, if the agency is committed to making a change in its interpretation of the law in this area, Johnson & Johnson urges FDA to do so in a way that comports with the language and intent of the Hatch-Waxman Amendments and maintains the carefully constructed compromises inherent in the Amendments. FDA's proposed rule regrettably falls short of that standard.

The proposal accomplishes its stated purpose by providing that the notice requirement of a Paragraph IV certification will not apply to amendments to ANDA or 505(b)(2) applications that already include a Paragraph IV certification. Without the notice to the NDA or patent holder, the 45-day review period does not begin, timely litigation cannot be initiated and the 30-month stay would not come into play. This reinterpretation of statute removes the possibility of multiple stays caused by the patent filing practices of NDA holders. At the same time, however, FDA's proposal creates a new and obvious loophole that could be used by generic drug applicants to preclude patentees from obtaining even a single 30-month stay. On its own accord, a generic applicant could effectively eliminate the 30-month stay possibility altogether simply by filing an initial ANDA or 505(b)(2) application with a Paragraph IV certification of non-infringement, then amending the application and certification. The patentee may, therefore, be under an erroneous belief that there is no infringement and consequently elect not to file suit within the 45-day review period. This result would violate both the language and the intent of the compromise struck in the Hatch-Waxman Amendments

and is inconsistent with FDA's stated goal to preserve the opportunity for patentees to obtain a 30-month stay.

This new loophole, which appears to be unintended, could prevent patentees from obtaining a 30-month stay under a variety of circumstances.³ For example, suppose an NDA holder has filed a patent for a particular solvent that is used in its approved drug product. Under this loophole, an applicant could file an ANDA for the drug that uses a different solvent and include a Paragraph IV certification that there is no infringement of the NDA holder's patent. Upon notice and investigation, the NDA holder may agree that there is no infringement, allowing the 45-day review period to end without the initiation of litigation, and thus never triggering a 30-month stay. Thereafter, the generic drug applicant, for whatever reason, may decide to replace its initial solvent with the NDA holder's patented solvent. The generic drug applicant would amend both its application and its Paragraph IV certification, although this time the certification likely would have to challenge the validity of the NDA holder's patent. Under FDA's proposed rule, the NDA holder/patentee would receive no notice of this amendment and would have no opportunity to obtain a 30-month stay to allow for litigation to defend its patent rights. That result would be contrary to the entire thrust of the Hatch-Waxman Amendments, which were intended to provide meaningful notice of patent disputes and an opportunity to resolve those disputes as soon as possible so as not to delay the market entry of non-infringing generic drug products.

This loophole is unnecessary and inconsistent with the intent of the Hatch-Waxman Amendments. Johnson & Johnson urges FDA to revise the proposed rule to eliminate this problem. Patentees should not be precluded from obtaining even a single 30-month stay when an ANDA or Section 505(b)(2) applicant chooses to alter its patent certifications for reasons other than the listing of a patent subsequent to the filing of that ANDA or 505(b)(2) application.

II. FDA should monitor compliance with Paragraph IV certification notice requirements and require provision of product samples.

FDA invited comment on whether to amend the existing regulatory requirements for the notice of Paragraph IV certification that must be provided to patentees and NDA holders. FDA should take action to ensure that ANDA and Section 505(b)(2) applicants provide notice adequate to enable meaningful assessment of the likelihood that the generic product infringes the patent. Timely notice with adequate information is needed to avoid unnecessary litigation and delay of generic product approval, both of which are stated objectives of FDA's proposed rule. In addition, as a matter of fairness, FDA should ensure applicants fulfill this statutory obligation, given the effect of the changes to the NDA holder and patentee rights and obligations the agency proposes to adopt. Accordingly, Johnson & Johnson urges FDA to monitor compliance with the notice

³ The PhRMA comments rehearse a number of examples that illustrate the range of this problem.

requirement and to further require ANDA and 505(b)(2) applicants to provide samples of their product upon request.

As noted in PhRMA's comments, the adequacy of Paragraph IV certification notices is highly variable. In the absence of complete information, NDA holders/patentees may have no choice but to bring a patent infringement action to avoid both losing their right to a 30-month stay and risking unrecoverable damage to the market for the drug product. Additional guidance for applicants could help. However, a significant current problem is the failure of some generic drug applicants to attempt to comply in good faith. Consequently, we urge the agency to monitor the adequacy of Paragraph IV certification notices.

We appreciate that FDA does not have the expertise or resources to assess whether a patent should be listed in the Orange Book, or to assess Paragraph IV certification notices in detail. However, a facial review of Paragraph IV notifications for adequacy would not require special expertise, could be incorporated into the application review process without a large additional expenditure of agency resources, and could have a significant salutary effect.

Regardless of whether generic applicants make good faith efforts to provide complete notice, however, the existing notification requirements are insufficient. Based on such notice, NDA holders/patentees can make no more than informed guesses in many cases as to whether the product may infringe the patent. FDA should, therefore, require ANDA and 505(b)(2) applicants to provide the NDA holder and patentee promptly, upon request, a sample of the generic product. This would not fully eliminate the challenge faced by the NDA holder/patentee in assessing whether to initiate litigation, but would be of substantial assistance.

In some, but by no means all, Paragraph IV patent infringement suits, the generic drug applicant agrees to provide a sample of its product to the NDA holder/patentee for testing. This can significantly expedite the litigation process, potentially reducing litigation time by many months or may even eliminate litigation. However, not only is this practice inconsistent, but when it does occur, it occurs too late to prevent the initiation of the litigation process. Receiving a sample promptly after receiving notice could provide the NDA holder/patentee enough time to test the sample and make a more informed determination of the likelihood of infringement before the end of the 45-day period for filing a claim without losing the right to a 30-month stay. In the absence of samples, a patentee may be compelled to bring litigation in order to obtain needed discovery and preserve their rights for an infringement action.

Such a requirement would be wholly consistent with the dual objectives of the Hatch-Waxman Amendments, to promote generic competition while allowing pioneers an opportunity to protect the intellectual property essential to innovation. It would reduce unnecessary litigation and the resultant 30-month stay to the benefit of generic drug manufacturers, pioneers and consumers alike. It is ironic, as well as unfair, that generic drug applicants can obtain and use samples of pioneer products to facilitate preparation of

their applications, but NDA holders and patentees cannot access samples of generic products as a means, potentially, to prevent litigation to the benefit of all.

III. FDA's proposed claim-by-claim patent declaration requirements are improper and unnecessarily onerous and expose NDA holders and patentees to needless risks.

FDA proposes to require NDA applicants to declare on a claim-by-claim basis why patents relating to their products meet the requirements for listing in the Orange Book. This requirement would be unnecessarily onerous, would threaten the patentee's legitimate patent rights and would expose the NDA holder to potential civil and criminal liability.

As discussed in the PhRMA comments, the requirement is unnecessary and improper. Any patent containing a single claim that meets the requirements for listing must be listed. The existing declaration requirement is, therefore, appropriate and adequate. In addition, many patents include dozens of claims or more. This could make compliance with the proposed declaration requirements an arduous process. Further, inadvertent failure to declare as to a particular claim could be viewed as an admission against interest that could preclude defending the patent with respect to that claim. Also, an NDA holder that makes a declaration in good faith regarding a claim that is subsequently found not to claim the drug could be exposed to civil and criminal penalties and liability, including making false claims to the government, fraud, and anti-competitive behavior.

Johnson & Johnson appreciates this opportunity to present its views to FDA on this topic of great importance to us and to the entire pharmaceutical industry.

Respectfully submitted,



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