defined structurally or in terms of a process – and the drug is the same as that in a pending or approved NDA, the patent should be listed.[9] The certification provided by the NDA holder will be sufficient to cover these points. There is no need for FDA to establish additional mechanisms to distinguish product-by-process patents from process patents. Indeed, it is difficult to envision any additional measures FDA could impose that would not plunge the agency inappropriately into complicated issues of patent law and introduce listing criteria alien to the statute.

C. Patents Claiming Drug Delivery Systems Are Listable.

A patent claiming a drug delivery system that is an integral part of the drug product is listable. Such patents differ from patents claiming only packaging and containers, which FDA explains in the preamble to the proposed rule are "distinct from the approved drug product" and do not "claim the drug." 67 Fed. Reg. at 65451. Examples of integrated drug delivery systems include, but are not limited to, asthma inhalation devices, nasal inhalers, trans-dermal patches, and pre-filled syringes. Patents claiming such integrated drug delivery systems claim the drug product, and should be listable, even if ordinary packaging and container patents are not. We do not understand FDA to be calling for a different approach in its proposed regulation.

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[9] This is true whether or not the process specified in the patent is the approved manufacturing process for the drug product. So long as the product claimed by the patent is the approved product, and an ANDA or 505(b)(2) application could be approved employing the process described in the patent, the patent should be listable.

the approved product, and an ANDA or 505(b)(2) application could be approved employing the process described in the patent, the patent should be listable.

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D. Patents Claiming an Approved Method of Using a Drug Product to Administer a Metabolite are Listable.

The proposed regulation would prohibit the listing of patents that claim metabolites and not an approved drug substance or drug product. Proposed 21 C.F.R. § 314.53(b). We do not construe this proposed regulation to prohibit the listing of a patent that claims a method of using an approved drug product to administer a metabolite. Such a patent claims an approved method of use of an approved drug product, and would be listed under proposed 21 C.F.R. § 314.53(b).

III. What Does the Patent Declaration Say? [Proposed § 314.53(c)(2)(i)]

A. FDA's Proposed Claim-by-Claim Declaration Requirements are Improper.

The proposed rule would significantly expand the information that an NDA sponsor must include in the patent declaration that is submitted with an NDA by requiring detailed information on each claim of a patent. This claim-by-claim declaration requirement is improper. Under the statute, patents – not claims – are submitted to the FDA for listing, and ANDA and 505(b)(2) applicants must provide a certification "with respect to each listed patent" – not a certification only to particular claims. FDCA §§ 505(b)(1), 505(b)(2)(A), 505(c)(2), 505(j)(2)(A)(vii). If a patent contains one claim that meets the requirements for listing, the patent must be listed. The proposal to require expansive claim-by-claim patent declarations thus goes beyond the statutory language and would not serve any statutory purpose.

FDA asserts (67 Fed. Reg. at 65453) that requiring submission of a claim-by-claim declaration would ensure that applicants submit only appropriate patents for listing. The agency offers no support for its assertion that the new declaration rules would promote

claim declaration would ensure that applicants submit only appropriate patents for listing. The agency offers no support for its assertion that the new declaration rules would promote

appropriate patent listings. The agency's suggestion (67 Fed. Reg. at 65454) that "precise identification" of patent claims may reduce infringement disputes also cannot support the agency's new proposed requirements. This rationale reflects an inappropriate attempt by the agency to influence patent infringement litigation, and is unrelated to the role assigned the agency under law with respect to patent listing.[10]

So long as FDA requires the applicant to declare that at least one claim of the patent supports listing, the statutory listing criteria are met. Requiring declarations to additional claims provides no further assurances for the propriety of the patent listing and merely increases the administrative burdens on applicants.

B. FDA Should Modify the Proposed Drug Substance Acknowledgement of "Sameness" Requirement.

For drug substance claims, FDA's proposed rule would require NDA sponsors to state whether the claim covers the active ingredient in the approved or pending NDA, or an active ingredient that is the "same" as the active ingredient in the approved or pending NDA. If the claim is for an active ingredient that is the "same" as the active ingredient in the NDA, the sponsor must "acknowledge that an ANDA or 505(b)(2) application containing the same active ingredient that is claimed by the patent is the 'same' for ANDA or 505(b)(2) approval purposes." This proposed pre-condition to the listing of patents claiming different drug forms is overbroad.

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[10] Whatever requirements the agency adopts for the declaration would not limit the claims that could be asserted in patent infringement litigation. NDA and patent holders remain free to assert all the claims of a listed patent in an infringement action whether or not a particular claim could have been listed with FDA standing alone. Of course, any patent whether listed or not can be enforced upon the marketing of an infringing product.

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a particular claim could have been listed with FDA standing alone. Of course, any patent whether listed or not can be enforced upon the marketing of an infringing product.

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FDA itself states that different drug forms of a drug substance (*e.g.*, polymorphs or hydration forms) *may* be the same active ingredient, and that whether they *are* the same active ingredient "is a scientific determination" based upon characteristics such as dissolution, solubility, and bioavailability. 67 Fed. Reg. at 65452. It is ultimately FDA's responsibility to determine whether different forms of a drug substance are or are not the "same" for purposes of ANDA approval. NDA holders should not be put in the position of having to state unequivocally that two drug substance forms are the same for purposes of ANDA and 505(b)(2) approval in order to list a patent. At most, NDA sponsors should be required to acknowledge that FDA has indicated that an ANDA or 505(b)(2) application containing the form of active ingredient claimed in a listed patent is or may be the same as the reference listed drug for purposes of approval.[11]

In contrast to the blanket acknowledgement that FDA has proposed, this modified declaration would reflect the inherent scientific uncertainty associated with different drug forms. Any acknowledgement that is required should be without prejudice to raising a later argument that an ANDA or 505(b)(2) application containing a different form of a drug substance should not be approved, for example, because of possible health consequences. If FDA were later to determine in a particular case that a form of the drug substance was not and could not be the same for purposes of approving ANDA and 505(b)(2)

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[11] For these same reasons, FDA should not require that NDA holders submit additional information regarding the basis for an assertion that drug substances are the same active ingredient. FDA invited comment on this issue in connection with its proposed rules for what patents must be listed. 67 Fed. Reg. at 65451.

ingredient. FDA invited comment on this issue in connection with its proposed rules for what patents must be listed. 67 Fed. Reg. at 65451.

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applications, the agency would presumably direct the NDA holder to delist patents claiming that drug substance form.[12]

C. FDA Should Clarify the Requirements for Providing Notice to the NDA Holder and Patent Owner.

FDA invited comment on whether the agency's current regulations regarding the notice that ANDA and 505(b)(2) applicants must provide to NDA holders and patent owners could or should be amended. FDA certainly has the authority to amend its regulations in this regard. The statute expressly provides that ANDA and 505(b)(2) applicants must include in their notice to NDA and patent holders a "detailed statement of the factual and legal basis" for an assertion that a patent is invalid or not infringed. FDCA §§ 505(b)(3)(B) & 505(j)(2)(B)(ii). This legislative language gives the agency all the authority it needs to establish reasonable rules to implement the notice requirement for paragraph IV certifications.

Moreover, it could be quite helpful for the agency to clarify the elements of a proper paragraph IV notification. The quality of paragraph IV notifications in practice is at best highly variable. Additional guidance from FDA on this issue would promote consistency and help ensure that paragraph IV notifications communicate meaningful information regarding the basis for an assertion that a listed patent is invalid or not infringed. ANDA and 505(b)(2) applicants should be required to include in a paragraph IV notice (1) an explanation of the relationship between the claims, as construed by the ANDA/505(b)(2)

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[12] Of course, a finding of non-bioequivalence with regard to a particular ANDA would not necessarily establish that the form of the active ingredient in the proposed generic could not be the same as the approved drug for purposes of ANDA submission in other cases.

Of course, a finding of non-bioequivalence with regard to a particular ANDA would not necessarily establish that the form of the active ingredient in the proposed generic could not be the same as the approved drug for purposes of ANDA submission in other cases.

applicant, and the aspects of the drug product for which approval is being sought, and (2) if applicable, an analysis of the legal bases upon which the patent claims might be deemed invalid or unenforceable based upon the construction of the claims provided by the ANDA/505(b)(2) applicant.

It would also be helpful for FDA to specify the rules regarding service of paragraph IV notices upon NDA and patent holders. There have been instances in which a notice of a paragraph IV certification was served upon an NDA holder but did not reach the proper location within the corporation in a timely manner, and the opportunity to bring a suit within the 45-day period and obtain a stay was inadvertently lost. These situations could be avoided if FDA were to require each NDA and patent holder to identify an agent to receive service of all patent notices from ANDA and 505(b)(2) applicants, just as FDA requires the identification of an agent for foreign patent owners, and to require ANDA and 505(b)(2) applicants to serve all notices on that agent by registered mail.

IV. FDA Has Adopted an Appropriate Implementation Plan.

PhRMA supports FDA's proposal to apply the proposed rules prospectively only. Indeed, prospective application of those aspects of the proposed regulation that truly are new (e.g., the 30-month stay provisions) would be required as a matter of administrative law. As the D.C. Circuit has explained, there is a basic "distinction between rules which create new legal obligations and those which simply restate or clarify existing statutes or regulations." *Chemical Waste Mngt. v. EPA*, 869 F.2d 1526, 1534 (D.C. Cir. 1989). Whereas interpretive rules clarifying existing law may be applied retroactively where reasonable, legislative rules establishing new rights and obligations, or significantly changing prior agency policy, may not. *See Williams Natural Gas Co. v. FERC*, 3 F.3d 1544, 1554

reasonable, legislative rules establishing new rights and obligations, or significantly changing prior agency policy, may not. *See Williams Natural Gas Co. v. FERC*, 3 F.3d 1544, 1554

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(D.C. Cir. 1993); *National Medical Care Inc. v. Shalala,* No. 95-0860, 1995 U.S. Dist. LEXIS 10074, *4 n.2 (D.D.C. June 6, 1995); *Alvarado Parkway Institute v. Mendex,* 789 F. Supp. 1190, 1195-96 (D.D.C. 1992).

Prospective application of the new rules also makes good sense as a matter of policy, and is consistent with FDA's approach in prior cases. As FDA explains in the preamble, retrospective application of the changes "would risk upsetting legitimate expectations held by those who had relied on our earlier interpretation of the act." 67 Fed. Reg. at 65457. FDA followed the same approach when it adopted a new interpretation of "court decision" for purposes of 180-day exclusivity and ANDA approvals. As the agency explained in its March 2000 guidance, "applicants who have made certain business decisions in good faith reliance upon an FDA regulation should not be penalized for their actions." Guidance for Industry: Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act at 4; *see also Mylan Pharm., Inc. v. Shalala,* 81 F. Supp. 2d 30, 45 (D.D.C. 2000) (indicating that it would be "inequitable to penalize" company that had endured lengthy litigation in reliance upon FDA regulation that had been upheld by circuit court).

Conclusion

PhRMA supports the agency's attempts to bring greater clarity to this important but highly complex area. Nevertheless, the proposed rule as currently formulated raises a number of significant issues with the potential to affect new drug innovation adversely. It is critical that FDA address these issues as it considers a final regulation.

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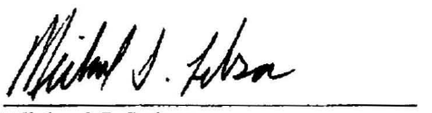
Respectfully submitted,



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COMMENTS ON FDA'S PROPOSED HATCH-WAXMAN REGULATIONS

This memorandum summarizes comments filed at FDA regarding the agency's October 24 proposal to amend its regulations implementing the Hatch-Waxman amendments.

1. aaiPharma

- Key points: FDA's current and proposed regulations fail to ensure that patent owners who are not also the NDA holder receive the rights provided to them by the statute. Opposes 30-month proposal; argues FDA must take steps to ensure NDA holders submit all (and only) listable patents.
- "FDA's abdication of its patent listing oversight duties" is contrary to the FDCA, is unlawful under the APA, and runs afoul of *Chevron*. (1)
- In particular, FDA regulations (current and proposed) "leave unaddressed an NDA holder's failure to list eligible patents known to FDA." (1) They also leave patent holders "without a remedy to correct improper failures to list." (2)
- FDA "must take steps to hold NDA holders accountable for fulfilling their obligation to submit patent information under the Act." (3)
- NDA applicants and holders that submit patent information on a polymorph (etc.) form of the drug substance "should be required to submit additional information regarding the basis for the assertion that the drug substances are the same". . . only when there is a legitimate question about sameness." (3-4)
- FDA's new interpretation of the statute (re 30-month stays) is "extremely strained" (4) and "would eviscerate a fundamental purpose of the Hatch-Waxman Act – *i.e.*, to ensure that the patent owner whose patent has been listed is aware of the ANDA and given the opportunity" to bring infringement litigation within the 45-day window and thereby obtain a stay. (5)
- The fact that Congress has proposed legislation to limit 30-month stays "supports the position that the Act must be amended by" statute "in order to impose such a limit." (6, n5)
- The switch in statutory interpretation "is a matter of political expediency"; the "sudden adoption of an opposite view without a reasonable explanation is clearly unacceptable under APA." (7)
- The agency should "more effectively police [ ] the completeness and accuracy" of Orange Book patent listings "rather than using an artificial limit on 30-month stays to discourage illegitimate patent listings." (18)

clearly unacceptable under APA. (7)

- The agency should "more effectively police [ ] the completeness and accuracy" of Orange Book patent listings "rather than using an artificial limit on 30-month stays to discourage illegitimate patent listings." (18)

2. **AARP**

- Key points: the final regulation should state explicitly that only one stay per drug product per ANDA is permitted; there should be a time after NDA approval after which the NDA holders should not be able to sue for patent infringement; legislation is necessary.
- FDA proposal "has the potential to begin closing loopholes that delay access to low-cost generics." (1)
- AARP agrees with proposal to permit only one stay per drug product per ANDA; agrees with "prohibiting 30-month stays for patents on process, packaging, metabolites, and intermediates." (1)
- "Language in the proposed regulation is open to multiple interpretations." (1) (no examples given)
- The regulation itself should state that "brand name manufacturers may be granted only one 30-month stay per drug per ANDA." (2)
- FDA should "consider alternative dispute resolution systems for timely and efficient challenges to FDA patent determination." (2)
- FDA should "limit the time after brand-name product approval in which additional patents may be listed in the Orange Book" and "limit the time after a generic application that a brand-maker may sue, regardless of whether a patent is eligible for a 30-month stay" – through regulation or if necessary legislation. (2)
- A legal challenge to the regulation is likely and could cause long delays.

3. **Academy of Managed Care Pharmacy (AMCP)**

- Key points: applauds the proposal; however, believes legislation is necessary; supports total elimination of 30-month stay.
- "Greater access to generic drugs can aid in restraining the unsustainable increases in prescription drug costs." (1)
- AMCP "applauds" FDA's effort "to provide consumers with more timely access to generic drugs." (1)
- AMCP "supports proposals that would accelerate the entrance of generic drugs into the marketplace and streamline the generic approval process." (2)
- Proposal "can mitigate some of the abuses" but "other abuses can only be addressed through legislative reform." (2)
- Patents are secured through PTO and listed in the Orange Book for "such questionable items as unapproved uses, unmarketed uses, changes to non-active ingredients, patient education kits that accompany the drug, and drug containers." (3)
- AMCP supports the "total elimination of the 30-month stay" because it "invites litigation regardless of the merits of the suit." (3)

- Patents are secured through PTO and listed in the Orange Book for "such questionable items as unapproved uses, unmarketed uses, changes to non-active ingredients, patient education kits that accompany the drug, and drug containers." (3)
- AMCP supports the "total elimination of the 30-month stay" because it "invites litigation regardless of the merits of the suit." (3)

- At the same time, legislation eliminating the 30-month stay should include "statutory provisions to ensure the timely resolution of reasonable patent disputes." (3)
- Alternatively, "the ability to delist frivolous patents becomes critical to ensuring timely generic drug entry into the marketplace." (4)
- AMCP supports S.812 with respect to180-day exclusivity. (4)

4. **Alfred Engelberg** (former patent counsel to GPIA)

- Key points: the proposal on 30-month stays will not accomplish its purpose of eliminating abuse of the 30-month rule and it is unlawful; a lawful and effective alternative would be for FDA to recognize that ANDA applicants are never required to amend their ANDAs to include new patent certifications.
- Late listed patents "usually cover formulations, metabolites, different crystalline forms ('polymorphs') and other subject matter as to which there is either no reasonable possibility of infringement or the patent is invalid because the claimed subject matter is not sufficiently different from that claimed in earlier patents. . . . The Bush/FDA proposal merely prohibits successive 30 months stays against the same ANDA. This would not prevent the belated assertion of non-meritorious patent claims in most cases. . . . Clearly, the obvious solution to the problem caused by the belated listing of non-meritorious patents is to directly deprive those patents of eligibility for the 30 month stay." (2)
- "A patent granted long after a new drug is approved has its full economic term and is not entitled to any special protections such as an automatic 30 month injunction." (2)
- "The Bush/FDA proposal conflicts with the basic intent of Hatch-Waxman that [sic] will not survive judicial scrutiny." The new interpretation is "pure semantic nonsense." (2)
- "Eliminating the requirement for notice following the filing of a paragraph IV patent challenge totally eliminates the possibility of expedited resolution and is inconsistent with the clear intent of the statute." (3)
- "[T]he Hatch-Waxman Act does not explicitly require an applicant for an ANDA to amend the patent certification that is required to be filed with the initial application. . . . Elimination of the requirement to file an amended certification for patents listed after the initial certification is filed would eliminate the possibility of 30 month stays with respect to belatedly-listed patent[s]." (3)
- "[A]ll patents that could reasonably claim some aspect of the new drug will normally be listed in the Orange Book long before any ANDAs are filed." (4)

patent[s]." (3)

- "[A]ll patents that could reasonably claim some aspect of the new drug will normally be listed in the Orange Book long before any ANDAs are filed." (4)

5. **Agvar Chemicals**

- Key points: supports S. 812 and generally opposes the FDA notice because it would not solve the problems with Hatch-Waxman and may distract from legislative efforts; different polymorphs and waters of hydration should not be listable; FDA should not permit listing of product-by-process patents for an active ingredient or formulation if there is already a listed patent that purportedly claims the active/formulation approved in the NDA; the new declaration requirements should apply to patents already listed in the Orange Book; FDA should accept paragraph (viii) statements from ANDA applicants for patents on unapproved uses; legislation is needed to deal with the 30-month stay issue and 180-day exclusivity problems, and to provide a mechanism for generics to challenge listings.
- FDA's proposal "would not resolve the problems that have developed since 1984, and would distract from necessary legislative reform that would solve the problems." (3)
- Legislation is still needed to address: inappropriate listings in the Orange Book, the lack of an effective mechanism for generic companies to challenge listings; use of the 180-day exclusivity provision to form anti-competitive arrangements between brand and generic companies; use of the 180-day provision to inappropriately delay generic drug competition in other situations (2); FDA should support reintroduction and enactment of S. 812 (3)
- Agrees with proposal regarding packaging, metabolites, and intermediates. Disagrees with proposal to permit listing of patents on chemical variants of active ingredients. (3) FDA's reasoning on the latter amounts to "injecting ANDA approval requirements into the interpretation of NDA content requirements – of which the patent listing criterion is a part" and is "unjustified." Moreover, "under FDA's logic – that listing a patent on an approved active ingredient is justified due to 'sameness' – it could be argued that listing a patent on an unapproved dosage form should be permitted due to the potential 'suitability' of an ANDA for that dosage form." Therefore, FDA should "adhere to its current interpretation of" Hatch Waxman by "limiting eligibility to patents that claim the active ingredient and formulation that are approved in the NDA." (4)
- With respect to Orange Book listings: "Generic companies have alternate sources of patent information." (4) Thus, "FDA would be ill advised to try to make Orange Book patent listing 'more useful' to generic companies by blurring the listing criteria, especially at a time when there are serious problems as a result of brand companies taking advantage of vague language in FDA's current listing regulations and FDA's unwillingness to police the listing process." (5)
- Agvar does not believe there are likely to be many active ingredients or formulations subject to NDAs for which there are proper product-by-process

make Orange Book patent listing 'more useful' to generic companies by blurring the listing criteria, especially at a time when there are serious problems as a result of brand companies taking advantage of vague language in FDA's current listing regulations and FDA's unwillingness to police the listing process." (5)

- Agvar does not believe there are likely to be many active ingredients or formulations subject to NDAs for which there are proper product-by-process

claims. Thus, before specifically allowing their listing, FDA should "investigate the types of product-by-process patents that have already been listed." (5) Moreover, "[a]t a minimum, FDA should not list a product-by-process patent for an active ingredient or formulation if there already is an Orange Book listed patent that purportedly claims the active ingredient or formulation approved in the NDA." (6)

- Agvar supports the more detailed patent declarations; these should apply to all currently listed patents as well. (6) This would not be "retroactive" application of a new rule, because the new provisions are simply "a clarification of the agency's existing requirements." (6)
- FDA's policy is not to accept paragraph (viii) statements from ANDA applicants for a patent that claims an unapproved use. This policy is unjustified and should be changed. "If the agency is not prepared to police Orange Book patent listings to screen out patents on unapproved uses, it should at least accept paragraph (viii) statements to those patents." (8)
- FDA has statutory authority to revise the notice provision to require specific types of information. (8) Amending the paragraph IV notice regulation to be more specific about the information the ANDA applicant must provide the NDA holder and patent owner would further Congress's goals. (9)
- "Later issued patents typically represent less significant scientific and technical work, and are more often of questionable validity based on patent law." (9-10) Giving an automatic stay to these patents is an "unjustified result." Although FDA "may believe that their proposal might reduce the magnitude of the 30-month stay problem," in fact "it would not deal with the fundamental problem of weak patents being artificially strengthened by the availability of an automatic preliminary injunction." (10)

6. **American Pharmaceutical Association (APhA)**

- Key points: supportive of FDA proposal; seeks clarification regarding method of use patents.
- APHA "appreciates" FDA's "efforts to increase access to generic medications." (1)
- Proposal is a "good step" in "creating a balance between" allowing access to generic alternatives and protecting innovation. (2)
- FDA should reexamine the listability of method of use patents and, in particular, clarify that the listability of these patents does not prevent manufacturers from obtaining approval of medications that use the same biological mechanism/pathway as approved drugs. (2)

7. **American Society of Consultant Pharmacists**

- Key points: generally supportive of FDA's effort; believes the S. 812 approach to 30-month stays should be used; also comments on federal

manufacturers from obtaining approval of medications that use the same biological mechanism/pathway as approved drugs. (2)

7. **American Society of Consultant Pharmacists**

- Key points: generally supportive of FDA's effort; believes the S. 812 approach to 30-month stays should be used; also comments on federal

reimbursement policies that are beyond the scope of the rulemaking. Good language on value of newer medicines for older patients.

- ASCP "appreciates and supports" FDA's proposal, which is an "important first step." (1)
- "ASCP understands the need for innovation among the pharmaceutical industry to encourage the development of medications that are more effective and cause fewer reduce [sic] side effects." (2)
- "While the older medications are available in less-expensive generic formulations, new medications often product better outcomes for seniors. For example, side effects from older medications for depression or psychosis may cause seniors to fall, resulting in hip fractures that could lead to death or permanent debilitation in seniors. Newer medications for these conditions do not have the severe side effects of some older medications but are much more expensive." (2)
- The FDA proposal is a "positive first step" towards the goal of putting generics on the market more quickly. (2)
- The recommended changes in FDA's proposed rule "will not only achieve costs savings, but will ultimately improve the health care of older Americans by increasing the affordability of necessary drug therapies." (5)
- ASCP supports FDA's proposal regarding patent listing, (5) because "it will significantly reduce the number of opportunities to list inappropriate patents as a means to prevent access to generic drug alternatives." (6)
- ASCP concurs with the goal of one 30-month stay, but the FDA proposal does not address limiting stays relating to late-listed patents. ASCP recommends that FDA incorporate the relevant aspects of S. 812 into its final rule: "brand manufacturers would be prohibited from claiming patent infringement, thereby being awarded an automatic 30-month stay, unless a patent was listed within 30 days of NDA approval." (6)

8. <u>American Association of Health Plans</u>

- Key point: short letter fully supportive of the proposal; no changes recommended.
- "We support the goal of the proposed rule to reduce the potential for inappropriate delays in the approval of new drug applications for generic drugs by revising certain requirements related to these applications. . . . We believe that the FDA's efforts to improve rules for bringing generic drugs into the marketplace can contribute to accessibility of beneficial prescription drugs to consumers." (1)
- "[R]eforms such as those proposed in this rule can foster increased patient access to generic medications without jeopardizing the vital role that the pharmaceutical innovation, reflected in the development of brand name drugs,

believe that the FDA's efforts to improve rules for bringing generic drugs into the marketplace can contribute to accessibility of beneficial prescription drugs to consumers." (1)

- "[R]eforms such as those proposed in this rule can foster increased patient access to generic medications without jeopardizing the vital role that the pharmaceutical innovation, reflected in the development of brand name drugs,

plays in our health care system. We urge the FDA move forward to refine the proposed rule and issue it in final form . . . ." (2)

9. **Apotex Corp.**

- Key points: opposes patent listing provision as too expansive; agrees with goal of one 30-month stay but has numerous concerns about interpretation and application of FDA approach; offers several alternate approaches; wants FDA to address 180-day exclusivity issues as well.
- FDA's proposal significantly and inappropriately expands the types of patent eligible for listing. Different forms of a drug are not eligible for listing. Product-by-process patents that claim old products are not eligible for listing. (2)
- Expansion of patent listings will lead to increased litigation, increased costs of generic entry, and delayed generic approvals. It could also create opportunities for additional periods of 180-day exclusivity that could delay generic entry for years. (4)
- "The patent eligibility criteria should not be widened to allow patents that claim different drug substances than the NDA approved drug substance to be listed." (5)
- "Different forms of drug substances should not be listed. . . . FDA has appeared to confuse the pharmaceutical equivalence requirement for the purposes of generic approval, with the Orange Book listing requirements. . . . FDA's Proposed Rule conflicts with the plain language of the Act and would be invalid. FDA's policy on equivalence is derived from an entirely different portion of the Act, is therefore irrelevant to this issue, and does not in any way support the Proposed Rule." (12) (see also 13, discussion of FDA reply to Apotex citizen petition)
- Product-by-process patents should not be listed in the Orange Book, or, alternatively, should be restricted to only those patents that claim a new product or new active ingredient." (5) (see also 15)
- Product-by-process patents should not be listed because "they are really process patents in disguise." (14) "[A]s a matter of substance, the invention . . . is that the process for making the drug substance is new." (14) "In the pharmaceutical industry, there are few (if any) active molecules that cannot be described in product terms." (14)
- "Listing of product-by-process patents that claim an already-patented active ingredient allows brand-name companies to obtain multiple 30-month stays. . . . Congress did not intend to provide the protection of a 30-month stay for old products." (15)
- NDA holders should be required to identify in their declaration: (1) the product-by-process claims of the patent, (2) the effective filing date of the application for patent, (3) whether the product has been previously sold, and

ingredient allows brand-name companies to obtain multiple 30-month stays. . . . Congress did not intend to provide the protection of a 30-month stay for old products." (15)

- NDA holders should be required to identify in their declaration: (1) the product-by-process claims of the patent, (2) the effective filing date of the application for patent, (3) whether the product has been previously sold, and

(4) if so, whether it was sold more than one year before the effective filing date of the patent application. If the answer to the latter is "yes," the patent should not be listable. (16)

- "[M]any later issued patents cover only minor modifications to the already approved product," (9)
- "Listings have another substantial effect" – on "the availability of 180-day exclusivity. "[I]f FDA expands the number of patents eligible for listing in the Orange Book, it will expand the opportunity for different applicants to obtain 180-day exclusivity." (9) "[I]n the event that a patent is listed in the Orange Book on the eve of generic approval, there is the potential for the first-filer on the last-listed patent to obtain a blocking right preventing other generic applicants (that have already submitted ANDAs and have already certified to any other relevant patent) from obtaining approval." (9-10)
- "[A]ny change to the regulations limiting the potential number of 30-month stays will be welcome." (4) "Apotex welcomes the intent of the [30-month stay] proposal." (17)
- "Apotex believes that the plain language of Hatch-Waxman only permits a single 30-month stay per ANDA. The issue is currently pending before the Federal Circuit . . . . " (17-18)
- If there are no patents in the Orange Book at the time the generic files its ANDA, the generic applicant should not be required to serve a paragraph IV certification to any patent listed thereafter. This could delay approval. Also, "[i]f all applicants are required to certify to the newly listed patent, the first to file a complete ANDA would be subject to being delayed approval until the expiry of the 180 day exclusivity period afforded the first filer to the newly listed patent." (18)
- "[T]he agency does not address what occurs when a notice is provided because the generic seeks to obtain voluntary pre-approval litigation of patent invalidity or infringement issues." (4)
- An ANDA applicant should be able voluntarily to deliver a certification to a patent listed in the Orange Book after the ANDA is filed, in order to obtain preapproval determination of infringement or invalidity. This should not trigger a further stay. (19)
- Apotex is concerned that if the patentee does not sue in this instance (or in the instance where there isn't even voluntary notice of the second certification), the ANDA may not be able to sue for declaratory judgment, because it may not be able to prove a reasonable apprehension of suit. (20)
- "The proposed rules should clarify that enjoyment of 180-day exclusivity is contingent upon serving a paragraph IV certification not only on FDA but also on the patentee and NDA holder." This will ensure that a first filer to a newly listed patent will not enjoy exclusivity that might block earlier generic applicants. (20)

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- FDA should ensure that "exclusivities relating to newly listed patents do not block generic applicants that have already filed ANDAs at the time the newly listed patent appears in the Orange Book and also to allow generic applicants that are not sued upon delivering a paragraph IV certification but are still delayed due to a first filer's paragraph IV certification, to trigger the first filer's exclusivity." (5)
- FDA should clarify the trigger of 180-day exclusivity when there are two patents listed at different times and the first filer on a second patent does not provide notice, is not sued, and chooses not to enter the market at risk (instead seeking a declaratory judgment). (21)
- "The statute also arguably contains timing restrictions on the eligibility of patents for listing in the Orange Book which would limit the number of patents that generic applicants would need to address when submitting an ANDA. This would practically have the effect of limiting generic applicants to having one 30-month stay of approval and also prevent later-issued patents from preventing generic entry by reason of the 180-day exclusivity provision." (4)
- "The Regulations should be amended to include timing restrictions on patents eligible for listing. Only patents that were issued at the time a NDA was approved should be listed, unless no patents were issued at the time of NDA approval, in which case the first issued patent would be listed." (5)
- FDA errs in its assumption that "but for the listing of [a] patent in the Orange Book, generic applicants would be unaware of [that] patent." "[W]hile the listing of patents at one time may have assisted generic applicants, that time has long since passed." (12)
- "Today, generic companies are substantial entities that conduct patent searches before applying for a product, and continue to monitor patent applications during the period an NDA is being reviewed by the agency." (13)
- Apotex offers a number of alternate ways for FDA to achieve its goal of one 30-month stay, including a reading of § 505(j)(5)(B)(iii) offered by GPhA. (22) Alternatively, FDA could use a "timing" approach, such that listing only applies to patents issued when the NDA is filed, patents issued before the NDA is approved if the NDA is amended prior to approval, and patents submitted to FDA 30 days after their issuance (if they were submitted to PTO prior to NDA approval and if no patents were issued prior to NDA approval). (22-25) Alternatively, FDA could choose not to require certification to newly-listed patents, i.e., patents listed after the NDA was filed. (25-26)
- FDA should change its policy permitting the listing of patents with a supplemental NDA, because these are patents that do not claim the innovator's drug *as originally approved*, and their listing is not authorized by the FDCA. (27) "[I]t is unlikely that research undertaken after an NDA is approved would product an advantage of the same magnitude as occurs with respect to the initial patent." (28)

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- FDA should address the problem that "the first to file on a later issued patent [may] receive 180-day exclusivity and [] prevent all other generics (who may have previously filed an ANDA before the time the new patent appears in the Orange Book), from receiving approval until a court decision in respect of the last issued patent or a first commercial marketing takes place by the first to file on the last issued patent." (29) Apotex suggests that FDA should in fact approve the earlier applicant, and that the subsequent applicant should be able to block approval of only applications submitted after it filed its own certification. (32) "This approach would mean that the first to file an ANDA containing a paragraph IV certification would not be blocked by a subsequent applicant that is the first to file on a newly listed patent." (33)
- FDA should also address the problem that arises when a generic applicant who files a subsequent ANDA and certifies to listed patents is not sued by the NDA holder, despite giving notice. "This means that the subsequent applicants may have no means to trigger the first filer's exclusivity and could potentially wait years to receive their approvals until the first filer's litigation is complete and the first filer has enjoyed 180-day exclusivity." (29) Apotex states that it is not clear FDA would view dismissal of a declaratory judgment as a court decision triggering exclusivity, and the agency should adopt a regulation "that provides that any dismissal of a declaratory judgment action on the basis of the patentee's admission of non-infringement and resulting lack of reasonable apprehension of suit by the patent holder, will be regarded as a court decision sufficient to trigger a first filer's exclusivity." (34-35)

10. <u>Barr Laboratories</u>

- Key points: endorses GPhA comments; writes separately (a 2-page letter) to highlight "interim" solution to the 30-month stay issue, which is to give ANDA applicants the option to file a second notice letter; endorses combined regulatory and legislative approach.
- Barr "commends President Bush and FDA for recognizing the need for immediate reform"; the FTC Report "confirmed that the patent listing and 30-month stay abuses are hindering competition and artificially maintaining monopoly prescription drug prices, to the detriment of consumers." (1) Barr is "extremely appreciative of the President's unprecedented efforts to restore the originally intended Hatch-Waxman balance." (2)
- For the reasons set forth in the GPhA comments, "revised regulations cannot give full effect to the President's goal of putting a stop to the gaming of the system that 'keep[s] generics off the market for frivolous reasons. [A] combined regulatory and legislative approach is the only effective means" of restoring the proper balance. (1)
- "Congress never envisioned *multiple* 30-month stays to be used to block generic competition, [but] we share GPhA's concern that the proposed rule's limitation on the 30-month stay could undermine the Hatch-Waxman goal of ensuring timely resolution of patent disputes." (2)

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- Barr proposes an "interim solution" – that ANDA applicants "be given a choice as to whether to file a second notice letter when an additional patent has been listed." . . . "As long as the choice belongs to the ANDA applicant, no harm should come from allowing the ANDA applicant to elect whether or not to file a second notice letter." (2)

11. <u>Blue Cross Blue Shield Association</u>

- Key points: BCBSA supports the goals of the proposed rule and wants it finalized with changes, but also supports legislation.
- Supports FDA proposal as "an important first step" that "can be strengthened" by adopting their recommendations; final regulation should be issued ASAP. (1)
- Supports goal of one 30-month stay. (2)
- Should be limited to patents filed within 30 days of NDA approval. (3)
- FDA should find a way to address timeliness of institution of infringement cases; if cannot, legislation should be developed. (3)
- Rule should be implemented with respect to all ANDAs, even those filed before effective date; existing multiple stays should be cancelled. (4)
- Patent declaration should include a statement that it is complete and accurate; FDA should "diligently enforce" timeliness of listing submissions. (4)
- Supports additional legislation. (5)
- Need a mechanism for delisting frivolous patents. (5)
- Need a time limit to ensure timely litigation, such as the 45-day statute of limitations "or other strategies." (6)
- Supports changes in the 180-day provision along the lines of S. 812 (e.g., forfeiture of exclusivity under certain circumstances, rollover to second-to-file in event of forfeiture). (6-7)

12. <u>Blue Cross Blue Shield of Michigan</u>

- Key points: supports 30-month stay proposal and listing proposal; has additional suggestions for the final regulation and for legislation.
- Commends FDA for proposed rule, "supports" the FDA proposal to allow only one 30-month stay when a generic company challenges a patent, and proposal "to set out rules for the listing of patents to ensure only appropriate patents are listed with the FDA" (1)
- Proposal is a "welcome step" that will aid in access to affordable prescription drugs (2)
- Requests additional provisions in final regulations: "requirements that patent declarations include a statement that complete and accurate patent information

patents are listed with the FDA" (1)
- Proposal is a "welcome step" that will aid in access to affordable prescription drugs (2)
- Requests additional provisions in final regulations: "requirements that patent declarations include a statement that complete and accurate patent information

has been filed" and "requirements that brand manufacturers register their patents with the FDA within 30 days of approval" (3) and "required disclosure on citizen petitions to indicate whether the petitioner has received or will receive remuneration for filing the citizen petition" (4)

- Recommends legislative changes: "method to address arrangements where brand-name manufacturers pay generic manufacturers to 'park' 180-day exclusivity" (4); FDA "should implement a stipulation that generic applicants that enter into such agreements forfeit their 180-day exclusivity" (4)
- Also other legislative recommendations: "process for generic manufacturers to challenge listability of patents under Hatch Waxman" and "process for removal of improperly listed patents" (5) and "requirement that brand-name companies and first generic applicants provide copies of certain agreements to the FTC" (6)

13. <u>Business for Affordable Medicine (BAM)</u>

- Key points: applauds the proposal, supports limit of one 30-month stay but says stay should only apply to patents listed before ANDA submission, wants FDA to establish a procedure for review of Orange Book listings and for delisting, believes legislation is still necessary.
- Proposal "is an important step to improve competition among pharmaceutical manufacturers and provide more timely access for pharmaceutical purchasers to lower-priced generic products." (1)
- FDA proposes the following changes: "clarify the types of patents that may be listed" . . . "*require drug companies to recertify that their patents qualify to be listed with the FDA*" [?] . . . and "limits stays on generic approvals" (2)
- "A process should be established to ensure the agency will not allow inappropriate listings in the Orange Book." (2)
- "We are also concerned that third parties, such as purchasers, have no standing to challenge abusive listings." (2)
- "BAM supports the proposed limit of one 30-month stay against generic products." However, remain concerned "that the limit will not prevent the use of 'late-listed patents' – those filed after generic applications are submitted – to obtain additional stays." FDA should restrict the patents that may trigger a stay to those listed prior to the filing of the relevant ANDA. (3)
- BAM is also concerned that the proposal "may encourage drug manufacturers to intentionally delay litigation on other patents until the end of any 30-month stay." (30)
- On patent listing: "present system actually encourages drug companies to unlawfully list patents in order to delay generic competition." (3)
- "BAM is concerned that the proposed regulations provide no mechanism by which FDA may refuse to list unqualified patents, or remove patents that are

to intentionally delay litigation on other patents until the end of any 30-month stay." (30)
- On patent listing: "present system actually encourages drug companies to unlawfully list patents in order to delay generic competition." (3)
- "BAM is concerned that the proposed regulations provide no mechanism by which FDA may refuse to list unqualified patents, or remove patents that are

unlawfully listed." FDA should establish "an administrative process to prevent such listings and to remove them when necessary." (3)

- "[L]egislation is necessary to ensure more effective and comprehensive reform. Legislation is also necessary to provide statutory authority to FDA to enforce its patent listing rules, to provide avenues for challenging unlawfully listed patents, and to address other shortcomings in the present law." (4)

14. Care

- Key point: email message; supportive of FDA proposal.

15. Caterpillar, Eastman Kodak, and General Motors

- Key points: supports the proposed rule, with modifications. Innovators should be required to recertify currently listed Orange Books with the new declaration (modified as recommended); FDA should develop the expertise to oversee the patent listing process; the new 30-month stay rule could lead to further delays (but this coalition still supports it); patents for unapproved uses that do not require clinical trial data should be added to the inventory of patents that may not be listed.
- Coalition "applaud[s] the FDA's administrative effort," which is an "important, but incremental first step." . . . "[M]ore can and should be done through this venue. . . . [C]ertain changes likely will require legislative action and [we] encourage the FDA's support in this regard." (2)
- "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." (2)
- "[G]overnment oversight" of the listing process is "necessary." "[F]or 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." (3)
- FDA "must have the capacity to advise companies to remove ineligible patents from the Orange Book listing or delist them itself." (3)
- 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)
- "[T]here are administrative options the FDA should explore to establish an effective oversight function." . . . One possible resource "could be" the PTO Legal Department. Alternatively, FDA could "reorder its priorities to fund such an activity" or "seek the necessary additional funds from Congress." (4)
- The patent declaration should be modified to reflect more completely the § 314.53(b) "do's and don'ts." Thus it should elicit an express statement "that no patents ineligible for listing are or will be declared for listing." It should "require applicants to identify published pending patent applications, and state

[illegible] Legal Department. Alternatively, FDA could "reorder its priorities to fund such an activity" or "seek the necessary additional funds from Congress." (4)

- The patent declaration should be modified to reflect more completely the § 314.53(b) "do's and don'ts." Thus it should elicit an express statement "that no patents ineligible for listing are or will be declared for listing." It should "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." (4)

- Patent declaration should also be signed as a certified statement with an acknowledgment clause (they offer a model). (5)
- "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." However, "we also support the FDA's conclusion that multiple 30-month stays were not intended by the Hatch-Waxman Amendments." (5)
- Has concerns that the one-stay provision "may cause additional delays that FDA intends to avoid." (5) "[T]he 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. . . ." but coalition "recognize[es] that the FDA is limited in what it can do to address" the issue. (6)
- Invites FDA to consider administrative measures to address abuses of 180-day exclusivity highlighted in the FTC Report. (5)
- Supports proposed modifications regarding patent listing. Final Rule should also expressly exclude from Orange Book listing eligibility patents obtained for uses not approved by the FDA. Also, listing should not be an option for polymorph patents and method of use patents, when the polymorph drug or new method of use does not require clinical trial data for FDA approval.

16. <u>Coalition for a Competitive Pharmaceutical Market (CCPM)</u>

- Key points: Proposal helps, but is not enough to close all loopholes; need to ensure timely resolution of patent disputes; if this can't be done by FDA, CCPM supports legislation.
- "CCPM applauds the Administration for issuing a proposed rule to address some of the abuses." (2)
- Supports intellectual property protections; "robust competition is the engine that drives innovation;" "absence of competition [in the pharmaceutical market] stalls innovation and the cost savings that can be achieved." (2-3)
- Proposal "does not completely close the loopholes that are being exploited to delay legitimate competition;" legislation is necessary. (4)
- Supports FDA on packaging, metabolite, and intermediate patents; disagrees on polymorph and product-by-process patents. (5)

- Proposal "does not completely close the loopholes that are being exploited to delay legitimate competition;" legislation is necessary. (4)
- Supports FDA on packaging, metabolite, and intermediate patents; disagrees on polymorph and product-by-process patents. (5)

- FDA oversight of patent listings is needed, especially because "generic manufacturers have no legal recourse to challenge the appropriateness of a patent listing in court." (6)
- Agrees with strengthening the patent listing declaration. (7)
- 30-month stay proposal is a "significant improvement," but it "may alter the fundamental balance of Hatch-Waxman." (7)
- Without the incentive of a new 30-month stay, brand companies will "wait as long as possible before suing on any reasonable patents that are listed after the first 30-month stay has begun." This will delay generics even more than the current system. The rule for one 30-month stay must be coupled with "measures to ensure timely resolution of patent disputes." (8)
- If this is outside FDA's authority, "CCPM encourages the FDA to support legislation;" CCPM also supports other legislative measures, such as 180-day reform. (9)

17. **Consumers Union (CU) & Consumer Federation of America (CFA)**

- Key points: recommends legislation to wholly eliminate 30-month stay; supports Leahy bill; agrees with FDA on packaging, metabolite, and intermediate patents; disagrees on polymorph and product-by-process patents; opposes FDA proposal on 30-month stay for same reasons as GPhA (no certainty for generic applicants on subsequent-listed patents).
- CU/CFA "applaud" FDA for "attempting" to focus on these issues; however, "the regulatory approach has significant limitations" and "the specific proposals contain serious flaws." (2) Proposed rule is "unlikely to significantly reduce the anticompetitive tactics that have been used to delay market entry of generic drugs, and may actually encourage these tactics in some cases." (2-3)
- Concerned about proposal's vulnerability to legal attack. (3)
- The FTC "issued recommendations for legislative changes" (emphasis in original). (3)
- Supports FTC recommendation that certain between innovator and generic agreements be filed with the FTC and the DOJ; endorses Leahy bill. (3, n5)
- Supports proposal provisions regarding non-listability of "product packaging or containers, metabolites, and intermediates." Also supports proposal to require more detail in patent declarations, but believes FDA should "develop a procedure to review listings." (4)
- Does not support proposal "to require additional patents to be listed in the Orange Book." Product-by-process patent and polymorph patent listings "should not be considered to be proper listings." (5)
- Although the FTC recommended clarification on the difference between process patents and product-by-process patents, it is "unlikely" that FTC

procedure to review listings." (4)
- Does not support proposal "to require additional patents to be listed in the Orange Book." Product-by-process patent and polymorph patent listings "should not be considered to be proper listings." (5)
- Although the FTC recommended clarification on the difference between process patents and product-by-process patents, it is "unlikely" that FTC

intended FDA "to simply allow the listing of all product-by-process patents." (5-6)

- The proposal to require listing of polymorph patents "appears to be an inadvisable blending of patent and FDA bioequivalence concepts." (6)
- Believes the 30-month stay is "unjustified" and should be eliminated through legislative changes. (7) Regardless, there should also be an enforcement mechanism, a disincentive for improper patent listing and late-listing of patents, and a "mechanism to require the resolution of patent infringement disputes in a timely manner." (8)
- The proposal regarding 30-month stays would not give generic applicants the certainty they need to enter the market, because the NDA holder would not be required to bring suit in a timely manner when it listed another patent in the Orange Book (same as GPhA's argument). (8-9)

18. <u>David Eichenauer</u>

- Key point: one paragraph letter; agrees with 30-month proposal.

19. <u>Families USA</u>

- Key points: supports clarification on types of patents that may be listed but opposes inclusion of product-by-process and polymorph patents; calls the proposed patent certification a "good step" but insufficient without FDA review of listability; supports the proposed 30-month stay limitation "in principle" but has same concern as GPhA that it will in some cases eliminate the mechanism for timely resolution of patent disputes.
- "[W]e support the proposal to amend the current listing regulation to clearly state that patents claiming metabolites, packaging, and intermediates are ineligible for Orange Book listing. However, we do not support the inclusion of product-by-process patents and patents claiming a different form of the approved drug substance ('polymorph' patents) among the patents that must be listed." (2)
- "The proposal to include product-by-process patents among patents that must be listed is not only contrary to the legislative history of Hatch-Waxman, but will likely lead to confusion among, and abuse by, NDA holders." (2)
- "[I]t has been the FDA's longstanding position that patents must claim the <u>approved</u> drug product or the drug product that is the subject of the application." (2) Therefore, "patents claiming different polymorphs should not be listed." (3)
- "The Patent Certification Statement is a first step but does not go far enough. It falls short of a real review of patent listability. . . . The FDA should go beyond merely requiring a statement from NDA holders and establish an administrative procedure for real review of listability, with delisting for those patents that do not meet listing requirements." (3)

not be listed." (3)

- "The Patent Certification Statement is a first step but does not go far enough. It falls short of a real review of patent listability. . . . The FDA should go beyond merely requiring a statement from NDA holders and establish an administrative procedure for real review of listability, with delisting for those patents that do not meet listing requirements." (3)

- Families USA believes that "no 30-month stay provision is necessary." Within the context of the rulemaking, Families USA believes that limiting NDA holders to one stay per drug product per ANDA is "an appropriate interpretation" of the law, but may result in "further delays in consumers' access to generics." (3) This is because it "may remove the mechanisms that currently allow ANDA applicants to have a resolution to legitimate patent disputes before going to market." (4)
- Either through rulemaking or legislation, ANDA applicants should have the option to certify to patents listed after the initial paragraph IV certification and to seek declaratory judgment if the NDA holder does not bring suit within a specific time period. (4)
- Legislation is needed to either remove the 30 month stay or ensure that the limitation to one stay is not challenged in court. There should also be a requirement that NDA holders promptly list patents, provision for substantive review of listability, and a mechanism for ANDA applicants to challenge Orange Book listings. (4)

20. <u>Federal Trade Commission</u>

- Key points: FTC supports the 30-month stay proposal and does not argue for legislation; FTC opposes proposal to allow listing of polymorph and product-by-process patents.
- Thirty-month stay proposal "is an important reform that would eliminate a substantial portion of the potential for unwarranted delay" identified in the FTC Study. (2)
- "[T]he FDA proposal [re 30-month stays] is an effective way to bring cheaper, generic copies of brand-name drug products to the market." (7)
- FDA proposal would have prevented multiple stays in 7 of the 8 cases identified in the FTC report (not for Platinol). (8)
- Patent listing proposals "provide needed guidance." (2)
- FTC supports FDA on packaging, metabolite, and intermediate patents. (9)
- Product-by-process patents are listable only if the product is novel, and not just the process. This should be implemented through enhanced patent declarations. (11, 13)
- FDA proposal "will eliminate most of the potential for 'gaming' the system . . . [but does not] completely fix the problem" where a patent is issued late and there is only a paragraph III certification to earlier patents. Therefore, patent listing requirements must be tightened. (8-9)
- Different polymorphs should not be listable. (13) Paxil example. (15)
- H-W intended to encourage "design-arounds" – patents covering these should not be listable; listing more patents won't conserve FDA resources; Orange

there is only a paragraph III certification to earlier patents. Therefore, patent listing requirements must be tightened. (8-9)
- Different polymorphs should not be listable. (13) Paxil example. (15)
- H-W intended to encourage "design-arounds" – patents covering these should not be listable; listing more patents won't conserve FDA resources; Orange

Book listing isn't necessary to provide notice to generics; serious harm to generics if these patents form basis for a 30-month stay. (17)

- Patents subject to terminal disclaimers for obviousness-type double patenting should not be listable. (18)
- Patent declaration should be signed by senior or outside patent counsel, who should attest to familiarity with listing requirements. (19)
- Claim-by-claim declaration is desirable; 30-month stay should be available only for suit on claims that are listable, not on unlistable claims just because patent has other, listable claims. (21)

21. Fish & Richardson

- FDA should await the outcome of Warner Lambert v. Apotex and Allergan v. Alcon, in the Federal Circuit.

22. Food Marketing Institute

- Key points: not a detailed response to the proposal, mostly a discussion of FMI's interest (FMI's retail members operate in-store pharmacies) and the need for reform; supported legislation last year (presumably S. 812); supportive of the proposed rule; believes additional legislative reform is necessary.
- "FMI wishes to convey our industry's strong support for FDA's proposed rule because it seeks to address certain shortcomings or unintended consequences in current law that deny consumers access to more affordable prescription drugs. . . . FMI has been extremely supportive of both legislative and regulatory reforms that are designed at promoting fair and equitable competition for pharmaceutical products. . . [W]e endorsed legislation in the 107th Congress that would close loopholes in the Hatch-Waxman law that allow brand-name companies to unfairly delay less expensive generic drugs from entering the marketplace." (2)
- The savings projected by the White House "are clearly realistic and achievable." (2)
- "The law performed extremely well up until about five years ago when certain brand-name companies began to file questionable last-minute patents that effectively blocked a generic from being introduced." (2)
- "FMI believes that these proposed revisions would begin the process of bringing much needed reform toward curtailing abuses that are occurring in the system. It is our view that the FDA rulemaking is very timely because without reforming Hatch-Waxman, it will become increasingly more difficult for consumers to obtain prescription drugs at affordable prices." (3)
- Additional legislative reform is needed. (3)

23. Generic Pharmaceutical Association (GPhA)

the system. It is our view that the FDA rulemaking is very timely because without reforming Hatch-Waxman, it will become increasingly more difficult for consumers to obtain prescription drugs at affordable prices." (3)

- Additional legislative reform is needed. (3)

23. Generic Pharmaceutical Association (GPhA)

- Key points: GPhA opposes the 30-month stay proposal on the ground that brand companies would delay filing infringement cases without the opportunity for a new stay; comprehensive legislative reform along the lines of S. 812 is needed.
- Patent listing and declaration proposal, with some changes, would be helpful; 30-month stay proposal, however, could "cause further imbalance in the Hatch-Waxman system by impeding the ability of generic companies to obtain timely resolution of legitimate patent disputes." (3)
- "Legitimate" patent dispute means one over a patent that meets the statutory listing criteria and "presents significant corporate exposure to the generic company which must be eliminated prior to product launch." (4, n2)
- "GPhA applauds FDA's recognition that brand companies have manipulated the 30-month stay provisions." The proposed rule, however, is problematic because (1) it may undermine the goal of preventing delays and (2) it "is likely to face, and may not withstand, a court challenge." (25)
- Early litigation and resolution of patent disputes gives generics the certainty they need to go to market. (26)
- The only reason brand companies list patents and file suits soon after getting notice is to get the 30-month stay. (26-27)
- FDA proposal may make it easier for brand companies to delay generics by removing incentive for timely litigation; this will encourage delays in bringing cases. (4)
- Without the stay, there will be no incentive to list or sue early; "brand companies would quickly adopt a new strategy to delay generic market entry: sue on the 30-month stay patent, but delay listing or suing on remaining patents until after the expiration of the 30-month stay." This would "introduce an entirely new element of uncertainty and risk" for generics. (27)
- Because of huge damages exposure, "generic companies have rarely ever marketed a product before resolving legitimate patent disputes with the brand company. And for this reason, significant uncertainty about patent liability will likely prevent generic companies from launching any affordable products." (7)
- Hatch-Waxman "is designed to eliminate this uncertainty early in the process" by creating "a framework for patent litigation to proceed concurrently with FDA's consideration of the generic ANDA." (7)
- At a minimum, FDA should allow generics voluntarily to submit a notice and subject themselves to a new 30-month stay on late patents. (6, n4) Generic should be permitted to provide notice voluntarily and thereby trigger a 30-month stay. (28)
- FDA's approach might preclude generics from being able to file declaratory judgment actions; fn. 16: even under the current system, the availability of a

- At a minimum, FDA should allow generics voluntarily to submit a notice and subject themselves to a new 30-month stay on late patents. (6, n4) Generic should be permitted to provide notice voluntarily and thereby trigger a 30-month stay. (28)
- FDA's approach might preclude generics from being able to file declaratory judgment actions; fn. 16: even under the current system, the availability of a

declaratory judgment action is "far from certain" because of the difficulty of meeting the "subjective standard of proving a reasonable apprehension of a suit." (28-29)

- FDA's approach might also cause problems with the 180-day exclusivity provision. (29-30)
- It is important to eliminate gaming by use of multiple 30-month stays, but FDA's approach is flawed; therefore, "GPhA does not endorse this portion of the proposed rule and urges FDA to withdraw it." (30)
- GPhA supports the S. 812 approach regarding patents eligible for 30-month stay and 45-day statute of limitations; fn. 17: proposed rule allows frivolous late-listed patent to get a 30-month stay if no previous patents were challenged; fn. 18: another approach is to allow declaratory judgment actions if patent holder fails to sue within a specified period (also was in S. 812). (31)
- FDA proposal also "leaves untouched" the ability of brand companies to list a frivolous patent late and get a 30-month stay if previous patents haven't been challenged. (4-5)
- The only viable option is legislative reform that encompasses the twin goals of "preventing gaming of the Hatch-Waxman system *and* ensuring that brand companies act quickly to list and litigate their patents." (5)
- Patents are listed that don't meet statutory or regulatory listing criteria. (11)
- Brand companies time listings "to obtain unwarranted extensions of their market exclusivity." (11)
- FTC reviewed these practices; most later-issued patents raised listability questions. (12)
- "[B]rand manipulation of the Hatch-Waxman system is made possible, in part, by FDA's refusal to review Orange Book listings and by the lack of a mechanism by which generic companies or others may challenge the validity of such a listing." (13)
- There is no private right of action- to delist; suit under the APA is possible but unlikely to be successful. (14)
- GPhA supports FDA on metabolite, packaging, and intermediate patent listings and opposes FDA on the listability of polymorph and product-by-process patents. (15)
- GPhA endorses the FTC's analysis of the polymorph patent issue. (16)
- "The fact that a polymorph is therapeutically equivalent to an approved drug product does not change the fact that listing of polymorph patents is contrary to the FFDCA's patent listing criteria, which require that a patent 'claim' an approved drug product." (18)
- Orange Book listing is not required to provide notice to generics. (19-20)

- "The fact that a polymorph is therapeutically equivalent to an approved drug product does not change the fact that listing of polymorph patents is contrary to the FFDCA's patent listing criteria, which require that a patent 'claim' an approved drug product." (18)
- Orange Book listing is not required to provide notice to generics. (19-20)

- Generics perform due diligence searches, including of patent applications published 18 months after filing under 35 U.S.C. § 122, "thereby enabling generic companies . . . to review a patent application's contents before the patent is issued by PTO." (20, n14)
- Brand companies "have succeeded in disguising process patents . . . as product-by-process patents;" FDA must provide guidance on distinguishing genuine product-by-process patents from process patents – and should use GPhA's proposed declaration from January 2002. (21-22)
- FDA must review patents to determine if they are listable; Biovail/Tiazac example. (23)
- At least, FDA must use the new declaration as a basis for refusing to list patents. (24-25)
- Comprehensive legislative reform is needed. (32)
- FDA proposal would likely be challenged in court and may not survive. (32)
- New interpretation is complete reversal of old view and would be unlikely to get deference in court; strained interpretation of "to include;" courts "have not hesitated to strike down Agency interpretations." (33-35)

24. <u>GlaxoSmithKline</u>

- Key Points: GSK generally endorses the FDA proposal, including with respect to listability of patents and the 30-month stay; however: GSK objects to FDA's characterizations of the representations it made in connection with the Paxil listing; FDA's statement that different forms of the active ingredient than found in the marketed product is not a change in policy; there is no reason why a good faith patent listing should estop the patent holder from objecting to ANDA eligibility or advocating that additional data be presented for a determination of sameness; claim-by-claim listing is not appropriate or consistent with the statute; patents covering devices or containers that are integral parts of the drug delivery system; the new regulation should apply only prospectively to NDAs and patents filed after the regulation's effective date.
- GSK "supports the comments submitted by" PhRMA and comments separately on several issues "in which it has a unique interest." (2)
- In regards to Paxil, "GSK from the start unambiguously informed FDA that the listed patents claimed a different crystalline form than that marketed in Paxil"; FDA's suggestion to the contrary in its proposed rule is incorrect. (3)
- FDA is correct that "patents must be listed if they claim the drug substance or active ingredient of an approved drug product, or if they claim the drug substance that is the component of such a product. Moreover, the relevant case law has supported the listing of patents claiming alternative crystalline forms of the active ingredient of the approved drug product." (4)

Paxil"; FDA's suggestion to the contrary in its proposed rule is incorrect. (3)

- FDA is correct that "patents must be listed if they claim the drug substance or active ingredient of an approved drug product, or if they claim the drug substance that is the component of such a product. Moreover, the relevant case law has supported the listing of patents claiming alternative crystalline forms of the active ingredient of the approved drug product." (4)

- FDA's proposed rule allowing for submission of information on patents claiming alternate crystalline forms "would do not more than clarify FDA's current policy." (5) Discussion of Apotex citizen petition. (5-6)
- FDA must clarify that patents claiming alternate crystalline forms have always been listable under part agency practice and interpretation. (6)
- Listing of polymorphs does not preclude challenging ANDA eligibility – "[T]here may be situations where polymorphic forms of a substance may differ materially in their clinical profile, and, therefore, there may be instances in which a polymorphic form may not be ANDA-eligible. Because the question of 'sameness' for alternative solid state forms may not be settled at the time patent listing is required, and indeed may be the subject of future administrative or legal proceedings, GSK believes that the new rule should not condition polymorph patent listing on a concession of ANDA eligibility." (7)
- The proposed requirement for listing individual claims is inappropriate and inconsistent with the statute; a reasonable requirement would be to identify one claim that is listable. (7)
- Product-by-process patents are listable; and there is no basis in patent law for treating them differently as unlistable process patents. (7) The appropriate test for listing product-by-process patents is that set forth by the Agency for the listing of product patents. (8)
- Patents covering devices or containers that are integral to a drug delivery system are properly listed in the Orange Book. (8) Examples include asthma inhalation devices, nasal inhalers, transdermal patches, and prefilled syringes. These delivery devices are critically related to the bioavailability and thus the safe and effective administration of the drug. (9)
- FDA must continue to apply its current regulation to pending NDAs; the new rule can apply only prospectively, or the agency will upset legitimate expectations held by those who acted in reliance on its earlier interpretation of the Act. (9)

25. **Greenblum & Bernstein**

- Key points: FDA should ground its 30-month stay proposal in a different theory (that certification on late listed patents is not an act of patent infringement); a stay should not be available in suits on claims that the NDA holder has not represented to cover the approved product; the patent declaration requirement should apply to all patents already in the Orange Book; and legislation is still needed to eliminate 30-month stays and give generics a mechanism to delist patents.
- If FDA wants the new regulation governing 30-month stays to pass judicial review, then it must admit that its earlier interpretation was incorrect. There is better support for the new proposal than that cited by FDA. In particular, 35 U.S.C. § 271(e)(1) makes it an act of infringement to submit an ANDA or a 505(b)(2) application. (2) "The technical act of infringement occurs, if ever,

Book; and legislation is still needed to eliminate 30-month stays and give generics a mechanism to delist patents.

- If FDA wants the new regulation governing 30-month stays to pass judicial review, then it must admit that its earlier interpretation was incorrect. There is better support for the new proposal than that cited by FDA. In particular, 35 U.S.C. § 271(e)(1) makes it an act of infringement to submit an ANDA or a 505(b)(2) application. (2) "The technical act of infringement occurs, if ever,

only when the ANDA is first submitted, and not at any time thereafter. Accordingly, it follows that if a patent is late listed, then, by definition, there is no infringement of the patent merely by a company already having an ANDA on file." . . . "Accordingly a reasonable interpretation of the statute is that only paragraph IV certifications in originally submitted ANDAs can lead to a 30-month stay of approval." (3)

- The new patent declaration form addressing specific claims "is a major conceptual improvement" because it "finally recognizes the importance of the individual claims of the patent." (4) However, there are no implications or consequences associated with the declaration. FDA should provide that "where the only claims being asserted in a listed patent are claims that the NDA holder has not represented to cover the approved product, . . . or an approved method of use, then such a suit should not be [the] basis for a thirty-month stay of approval." (4)
- FDA should not exempt approved NDAs from the patent declaration requirements, since there are "many questionable patents" already listed. Firm lists several options for applying the patent declaration requirement retroactively including, e.g., a timetable for all NDAs to submit patent declarations for listed patents. (5)
- Legislation is still needed; for example, the 30-month stay should be entirely eliminated, and there is no method for generic companies to seek delisting of inappropriate patents.

26. <u>Johnson & Johnson</u>

- Key points: endorses PhRMA comments; writes separately to add thoughts on FDA's proposed changes vis-à-vis the 30-month stay rule, the content of paragraph IV certification notices, and patent listing declaration requirements.
- Questions the need for FDA's proposal regarding 30-month stays. Points out the same loophole that PhRMA points out. (2) "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 Markey entry of non-infringing generic drug producers." Therefore, patentees "should not be precluded from obtaining even a single 30-month stay when an ANDA for 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." (3)
- FDA should ensure that ANDA and 505(b)(2) applicants provide "notice adequate to enable meaningful assessment of the likelihood that the generic product infringes the patent." (3) A facial review of notifications for adequacy "would not require special expertise" and could be incorporated into the application review process "without a large additional expenditure of agency resources." (4)

- FDA should ensure that ANDA and 505(b)(2) applicants provide "notice adequate to enable meaningful assessment of the likelihood that the generic product infringes the patent." (3) A facial review of notifications for adequacy "would not require special expertise" and could be incorporated into the application review process "without a large additional expenditure of agency resources." (4)

- J&J "urges FDA to monitor compliance with the notice requirement and to further require ANDA and 505(b)(2) applicants to provide samples of their product upon request." (3-4) "Receiving a sample promptly after receiving notice could provide the NDA holder/patentee enough time to test the same 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." (4)
- FDA's proposal that NDA applicants make claim-by-claim declarations "would be unnecessarily onerous, would threaten the patentee's legitimate patent rights [i.e., failure to declare could be viewed as an admission against interest], and would expose the NDA holder to potential civil and criminal liability." (5)

27. **Kos Pharmaceuticals**

- Key points: disagrees with FDA's proposal to eliminate multiple 30-month stays; proposal's provisions on patent listing are sufficient to prevent improper listing; proposed new interpretation of statute is plainly incorrect; elimination of stay will prejudice patent holders; little evidence that elimination of stay will result in greater availability of generic drugs.
- "FDA's interpretation of § 505(j)(2)(B)(iii) is incorrect and unnecessary to accomplish the FDA's goals. Amendment of [the listing regulations] would successfully prevent much of the abuse that the FDA has identified." (2)
- Proposal on listable patents and on patent declarations "will prevent the improper listing of patents in the Orange Book and will ensure that the marketing of generic pharmaceuticals to the public will not be unfairly delayed." (3)
- FDA's proposed amendments would have prevented Orange Book listing of four of the eight late-listed patents identified in the FTC Report. (4)
- "[L]ittle empirical evidence exists to suggest that the elimination of multiple 30-month stays in ANDA litigation [sic] will result in greater public availability of generic pharmaceuticals." (5) "[T]he stay imposed on ANDA approval resulting from patent infringement litigation has not been shown to delay the time that the generic drug is brought to market." (6)
- Requiring the NDA applicant "to include a more detailed declaration when submitting patent information for listing in the Orange Book will further reduce improper patent listings." (6)
- The FDCA "clearly dictates that an ANDA applicant must give the patent holder notice of any Paragraph IV certification, not just the applicant's original certification." (7)
- "[A] Paragraph IV certification with respect to one patent cannot address later-listed patents. For this reason alone, each Paragraph IV certification

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- "[A] Paragraph IV certification with respect to one patent cannot address later-listed patents. For this reason alone, each Paragraph IV certification

should be treated as a separate amendment that gives rise to a separate notice requirement and a separate 30 month stay on ANDA approval." (10)

- "The elimination of 30 month stays for legitimately late-listed patents will deprive a patent holder of a statutory remedy for infringement of its patents provided under the Hatch-Waxman Act and will penalize the patentee for delays in patent prosecution that it did not create. The FDA's proposal would also deprive the courts of their statutory power to determine the necessity of 30 month stays in a given situation, thereby discouraging the development of new drugs in general." (10)
- Under FDA's proposal, the "patentee would . . . be deprived of its statutory right to sue for infringement of its legitimately later-listed patent." (11) *(Ed note: reflects a misunderstanding of proposal, which does not affect the right to sue for patent infringement, only the opportunity for a stay of ANDA approval during litigation.)*
- "The courts, not the FDA, should determine whether to permit successive 30 month stays in ANDA litigation [sic]." (12) *(Ed note: this section of the comments reflects the mistaken belief that the proposal relates to stays of ANDA litigation rather than ANDA approval.)*

28. <u>Michigan for Affordable Pharmaceuticals</u>

- These comments are identical to the comments of Blue Cross Blue Shield of Michigan (see # 12).

29. <u>Mylan Pharmaceuticals</u>

- Key points: supports the proposal (except the 30-month provision) subject to some caveats, also supports legislative reform along the lines of S. 812. Proposes additional changes relating to 180-day exclusivity (use of court of appeals decision as exclusivity trigger) and 30 day listing deadline (withdraw NDA).
- "The FDA and the Administration should recognize the value in embracing <u>both</u> the limited regulatory reforms contained in the proposed rule (with the revisions noted below) and the more comprehensive reform that is possible only through legislation." (2)
- FDA should not permit the listing of patents that claim a different form of a drug substance (e.g., polymorphs, hydrates, and anhydrates). (3)
- "[W]holesale listing of product-by-process patents would have a profound negative impact on generic drug approvals. . . . Mylan proposes that only such patents in which the claims define the commercial product used to manufacture the approved product may be listed." (4)
- FDA should also exclude the listing of "other forms of an active which are not marketed form (i.e., acid, free base, salts, isomers), labeling matters (titration, dosing, registry, and business methods), and ornamental designs." (4)

negative impact on generic drug approvals. . . . Mylan proposes that only such patents in which the claims define the commercial product used to manufacture the approved product may be listed." (4)

- FDA should also exclude the listing of "other forms of an active which are not marketed form (i.e., acid, free base, salts, isomers), labeling matters (titration, dosing, registry, and business methods), and ornamental designs." (4)

- The declaration form should expressly exclude the listing of these nonlistable patents. (4)
- "While a single 30-month stay could prevent the prevalent practice of 'evergreening,' such an approach could nonetheless be subject to manipulation and abuse." (7) In particular, nothing requires the innovator to bring suit promptly on second patents. (7-8)
- "In order to restore the feasibility of successful patent challenges, the triggering event [for 180-day exclusivity] must be tied to an unappealable decision." (8)
- "FDA does not require ANDA applicants with pending applications containing valid certifications to certify to a new patent listing in the Orange Book that is submitted more than 30 days after patent issuance . . . FDA needs a better mechanism with which to penalize NDA holders who do not list patents in the Orange Book within 30 days of issuance . . . The *statutory* penalty for non-compliance would be withdrawal of the NDA." (9)

30. <u>National Association of Chain Drug Stores (NACDS)</u>

- Key points: more of an explanatory piece, comparing S 812 and the proposed rule; prefers S 812 approach to use of deadlines for patent listing and patent infringement suits; 180-day exclusivity issues need to be addressed and until Congress does so, FDA should permit rollover; FDA should clarify its role in reviewing patent listings; and ANDA applicants should be able to challenge improper listings.
- Proposed rule is a "positive first step" towards goal of "closing a number of loopholes in existing law." (1)
- Unlike S 812, the proposed rule "has no limitation on when a patent must be listed" in order to qualify for a stay, and it does not require the brand name manufacturer to sue in a timely fashion. FDA "should adopt patent filing provisions" similar to those in S 812. (2)
- Proposed rule does not address important issues relating to 180-day exclusivity. "[I]t is likely that sufficient incentives already exist in the market for generic manufacturers to challenge brand name patents," thus reducing the need for a market exclusivity incentive. "Settlement agreements between manufacturers are generally drafted with the goal of delaying generic marketing." Supports S 812 approach to rollover of 180-day exclusivity. Until Congress acts to address use of 180-day exclusivity to deter generic competition, FDA rules should allow for rollover of exclusivity. (2)
- Because FDA does not actively regulate patent listings, brand name manufacturers "have been able to use unrelated patent listings as the basis for infringement actions to delay generic marketing." (2) The final rule "should clarify the FDA's role in reviewing information listed." (3)

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- Because FDA does not actively regulate patent listings, brand name manufacturers "have been able to use unrelated patent listings as the basis for infringement actions to delay generic marketing." (2) The final rule "should clarify the FDA's role in reviewing information listed." (3)

- "New drugs that work by the same mechanism of action could potentially violate a method of use patent. . . . For method of use patents and all other patents, the FDA should clarify that the intent of the listing is not to stifle therapeutic alternatives." (3)
- ANDA applicants should be allowed to challenge improper listings. NACDS implicitly endorses S 812 approach to patent listing challenges. (3)

31. <u>New York State Department of Public Health</u>

- Key point: "enthusiastically" supports the proposal; offers no criticism.
- Proposal is "consistent with the New York State Medicaid program's efforts to enhance the use of generic drugs through the recent Mandatory Generic legislation." (1)
- Proposed clarification of listing requirements should be implemented "in order to prevent the delay of appropriate generic drugs from entering the marketplace." (1)
- Proposed patent declaration requirement "will ensure that appropriate patents are listed and will preclude any need for the FDA to decide patent issues." FDA lacks "patent expertise, resources, and any statutory mandate to scrutinize patent listings." (12)
- Proposal on 30-month stays :will assist New York State programs . . . to obtain less costly drugs." (2)

32. <u>Organon</u>

- Key points: opposes the proposal; FDA should withdraw the Proposed Rule or, at a minimum, (1) clarify that certain use patents are eligible for listing without regard to whether they claim an approved use, and (2) continue its longstanding policy of imposing a stay on ANDA approval whenever the ANDA (or an amendment to the ANDA) contains a paragraph IV certification.
- FDA proposal to bar listing of use patents other than those that claim an approved use "runs contrary to the plain language of the Hatch Waxman Act" (2) and "conflicts with the relevant provision of the Patent Act." (3)
- FDA's restriction on use patents also "upsets the delicate balance – carefully crafted by Congress – between drug innovation and the availability of generics." The legislative history of Hatch-Waxman demonstrates that Congress "took great pains to protect the substantial investment made by innovator companies by according them full patent rights in new drugs and uses for those drugs." (4)
- FDA's restriction on listing of use patents also conflicts with the goal of resolving questions of infringement prior to generic market entry. (4) "The effect of the regulation is to deny the potential for premarket resolution of the validity of the patent, forcing the generic company to choose between coming

innovator companies by according them full patent rights in new drugs and uses for those drugs." (4)

- FDA's restriction on listing of use patents also conflicts with the goal of resolving questions of infringement prior to generic market entry. (4) "The effect of the regulation is to deny the potential for premarket resolution of the validity of the patent, forcing the generic company to choose between coming

to market and facing massive damage claims or choosing not to proceed. This is precisely the dilemma that Congress sought to avoid in enacting the Hatch Waxman Act." (5)

- FDA's restriction on listing of use patents suggests the agency mistakenly believes that patent infringement cases arise only when an applicant submits an ANDA for a patented use claimed in an NDA. (5) In fact, infringement of patents for off-label uses is "entirely predictable," and "[w]here an NDA holder has exclusive patent rights in a particular use of a drug – whether approved or off-label – it may 'reasonably assert' those rights in connection with the marketing of a generic copy of that drug that likely will be prescribed for such use." (6)
- FDA's proposal regarding 30-month stays is inconsistent with longstanding agency policy. (7) It is contrary to the plain language of Hatch-Waxman and conflicts with Congress's intent as evident in the Act's legislative history. (8) As a reversal of prior longstanding agency interpretation, it is entitled to no deference. (11)
- FDA's proposal could enable ANDA applicants to avoid any stay under the following hypothetical: applicant files a flawed ANDA with an erroneous ¶ III, FDA refuses to accept the ANDA, applicant files an amended ANDA which includes a ¶ IV. Organon believes that no stay would be available under FDA's proposal in this scenario. (11) *(Ed note: this is a misreading of FDA's proposal. This would be an amendment to include a ¶ IV certification and would trigger a 30-month stay.)*
- The investments made by innovator drug companies in "legitimate reliance" on the established 30-month stay policy are endangered by FDA's proposal. (14)

33. <u>Pfizer</u>

- Key points: questions need for reform on 30-month issue; reserves judgment on whether FDA's revisions are legally appropriate; FDA should allow listing of patents that claim packaging and containers the agency would require prior approval for any changes in those elements; endorses PhRMA comments and concerns about generic manipulation of new interpretation of stay provision; FDA should provide notice to NDA holders for subsequent paragraph IV notifications; FDA should re-issue proposed rule for a second round of comments.
- "Pfizer urges FDA to consider carefully whether its proposals are necessary and proper to achieve the balance of competition and innovation embodied in the 'Hatch-Waxman' generic drug law." (1)
- The FTC Report's findings "indicate that only a tiny fraction of ANDAs have been subject to even one stay, and an even much smaller percentage (probably well under one percent) have experienced multiple stays." (3) "Pfizer respectfully submits that both the FTC and FDA have overstated the asserted

and proper to achieve the balance of competition and innovation embodied in the 'Hatch-Waxman' generic drug law." (1)

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'problem' of 30-month stays, and have rushed to a 'solution' that may be broader than warranted by the stay's experience as a feature of the Hatch-Waxman law. . . . Pfizer reserves judgment on whether, in a broad sense, the regulatory revisions FDA is proposing are necessary or legally appropriate."

- In some situations, a drug's container or packaging may be "integral to the product's use" (e.g., "novel blister packaging" or "a drug delivery system"). FDA should revise the proposed rule to allow listing of patents that claim "packaging, containers, or delivery systems, if FDA would require prior approval for any changes in those elements." (5).
- FDA should revise its regulation to permit patent listings in situations when the marketing of a generic drug for an approved use could infringe, by inducement, the patent covering an unapproved use. (6-8)
- NDA holders listing patents claiming alternate drugs forms should not have to assert that the alternate form is "the same" as the approved drug for ANDA approval purposes. (8) It is "inappropriate" for FDA to place the burden on the NDA holder "of making the scientific determination of 'sameness.'" Instead, FDA should allow the NDA holder "to list a patent claiming an alternative drug that *could* be considered 'the same as' the approved drug." (9)
- "[I]t is highly dubious that [the limitation to one 30-month stay] is necessary or appropriate." (10)
- The 30-month stay proposal creates the opportunity for an ANDA applicant to avoid any 30-month stay. "The regulatory revisions proposed by PhRMA should help correct this problem." (10)
- "Another serious flaw in the Proposed Rule is that, by eliminating the ANDA applicant's obligation to notify an NDA holder of new paragraph IV certifications, it may delay the initiation of patent litigation until after a generic drug enters the market." (10) "One way to correct this would be for FDA itself to notify the NDA holder about a patent challenge in an ANDA." (11)
- "Pfizer recommends that FDA re-publish the Proposed Rule for further comment before finalizing it." (12)

34. **Rx Health Value** (Verizon, GM, Ford, BCBS, etc.)

- Key points: questions value of any 30-month stay; agrees that one 30-month stay is appropriate alternative; believes there should also be mechanisms to force rapid resolution of patent disputes, along the lines of S. 812; innovators would not be prejudiced by immediate implementation; Administration should support legislation in light of widespread questioning of FDA's statutory authority.
- Rx Health Value "applauds" the Administration and FDA for acknowledging the need to update its regulatory approach. (1) Proposal is an "important first

would not be prejudiced by immediate implementation; Administration should support legislation in light of widespread questioning of FDA's statutory authority.

- Rx Health Value "applauds" the Administration and FDA for acknowledging the need to update its regulatory approach. (1) Proposal is an "important first

step" but FDA is "constrained by the limitations of the current statutory language." (2)

- RxHealth Value "continues to question the need for the automatic 30-month stay" but also believes that the limitation to a single stay "is the most reasonable and appropriate interpretation of the current law." (2)
- Any limitation on 30-month stays must include "safeguards to avoid collateral damage and ensure that the patent litigation and FDA review occur simultaneously so that affordable generic drugs reach consumers as soon as possible." RxHealth Value urges FDA to include provisions (from S. 812) that would (a) require NDA holders to list all patents within 30 days or lose the right to sue, and (b) require that suits against generics be filed within 45 days of challenge to the patent – or to support legislation doing so, if this is not within agency's statutory ability. (2)
- Rule can be implemented immediately – there is "no manifest unfairness" because branded manufacturers would still retain ability to litigate their claims. (3)
- FDA should take note of the widespread questioning of its statutory authority and take the prudent course of supporting appropriate legislative remedies at the same time. (3)
- "RxHealth Value is a strong supporter of intellectual property protection. Effective protection of patents is essential to assuring an incentive to develop innovative new drugs. We believe that such protection, including the Hatch-Waxman amendments, created an environment of remarkable innovation in the 1980s and early 1990s that led to the development of many effective new drugs, improving health care and quality of life for many Americans." (3)

35. **Teva**

- Key points: supportive of FDA effort but finds it doesn't go far enough; recommends a number of modifications and insists legislative reform is still needed. For example, opposes listing of polymorphs. Believes FDA's listing proposal could be read to allow NDA holders to list buffers, antioxidants and preservatives not used in the Reference Listed Drug. FDA should give more examples of nonlistable patents. Patent declarations should be made public when the NDA is approved. The agency should adopt a mechanism for reviewing listability and for delisting patents. FDA should adopt the listing declaration questions proposed by GPhA. Teva cannot support the 30-month proposal, because it doesn't give ANDA applicants a way to litigate subsequent-listed patents prior to market entry. FDA should make it clear that generic applicants may voluntarily provide optional notices and trigger stays. Various legislative reforms also required (including on 180-day exclusivity).
- Teva "commends FDA and the Bush Administration" for its efforts to rebalance the current generic drug approval system under Hatch-Waxman." The company is "pleased and encouraged by FDA's recognition . . . that the

subsequent-listed patents prior to market entry. FDA should make it clear that generic applicants may voluntarily provide optional notices and trigger stays. Various legislative reforms also required (including on 180-day exclusivity).

- Teva "commends FDA and the Bush Administration" for its efforts to rebalance the current generic drug approval system under Hatch-Waxman." The company is "pleased and encouraged by FDA's recognition . . . that the

current system of patent listing and 30-month stays is not operating as intended." (1)

- The proposal "would unlawfully expand the statutory provisions governing patent listing eligibility"; it "does not go as far as it could, and should, to provide for effective enforcement of the patent listing requirements"; and "legislative changes are necessary to fully restore the balance sought by Congress." (1-2)
- FDA has "abdicated its obligation to enforce" 21 U.S.C. § 355(b)(1), which states that only a "patent which claims the drug for which the applicant submitted the application" may be listed. (2)
- Teva "strongly opposes the proposal to allow listing of patents claiming a different form of the active ingredient approved in the NDA product (including, e.g., polymorphs, hydrates, and solvates), because such listing would be inconsistent with the statute, and because FDA's stated reasoning for this position could lead to an even broader range of irrelevant patents being listed in the Orange Book." (3) FDA's interpretation would effectively read out of the statute the term 'for which the applicant submitted the application.'" (4)
- "[A]s explained in the comments of [GPhA], FDA also confuses the difference between what it means for a patent to 'claim' a specific form of a drug substance, and for an alternative form of the substance to be bioequivalent to the form approved in the NDA for the brand product." (4, n3)
- "Under FDA's rationale – that patents may be listed if they claim an active component that might be included in a pharmaceutically and therapeutically equivalent generic product – NDA sponsors might seek to list patents on all possible buffers, antioxidants and preservatives even though they are not used in the Reference Listed Drug. (5) . . . FDA should clarify that to be listed in the Orange Book, a patent on a drug component (whether active or inactive) must claim a component that is actually approved in the reference NDA." (6)
- FDA "underestimates the legal sophistication and scientific acuity of the modern generic industry. Specifically, generic drug companies today spend millions of dollars per year in patent searches and analyses, not only to identify relevant issued patents, but to track pending U.S. and foreign patent applications that may impact their product development plans. . . . [N]o product generic applicant would rely solely on the Orange Book for a determination of its freedom to pursue a particular application." (6)
- FDA should identify (without limiting) other patents that are ineligible for listing, "for example: business method patents; and patents claiming substances which may or may not be present as impurities in a drug product ('impurity patents')." (6)
- Teva supports proposal to strengthen the patent listing declaration, with some modifications. (6) First, "in order for the revised patent declaration to serve

- FDA should identify (without limiting) other patents that are ineligible for listing, "for example: business method patents; and patents claiming substances which may or may not be present as impurities in a drug product ('impurity patents')." (6)
- Teva supports proposal to strengthen the patent listing declaration, with some modifications. (6) First, "in order for the revised patent declaration to serve

as a useful check on patent listing abuses, the declaration must be made public immediately upon approval of the NDA." (9) "Second, FDA should adopt a mechanism for reviewing the eligibility of patents for inclusion in the Orange Book, and for de-listing patents that are found to be ineligible." (10) Teva suggests use of an administrative law judge to review the patent and make a recommendation to the Commissioner. (10) This way, "FDA's decision would be subject to meaningful judicial review." (10) "Third, FDA should clarify and explain what degree of oversight FDA will use in reviewing the accuracy of patent listing declarations, and what if any remedy will be available for incorrect declarations that result in a patent being improperly listed." (10) In particular, the agency should commit to prosecuting false statements. "Fourth, FDA should fully adopt the listing declaration questions proposed by GPhA." (11) "Fifth, FDA should use this rulemaking to clarify and strengthen the Orange Book 'use code' mechanism to prevent abusive tactics by branded companies, such as listing use codes that are so broad that they overlap with other use codes, or use codes for unapproved indications." (11)

- Teva also "disagrees with FDA's suggestion that it lacks the *authority* to review patents for listing eligibility, and requests that the agency adopt a specific proactive mechanism for such review." (6) "The statutory listing provision is a mandatory, substantive requirement imposed upon NDA sponsors, and Congress has empowered FDA within at least one specific remedy for non-compliance with this provision – refusal to approve the NDA." (7) "[J]use because the courts have upheld, or commented favorably upon, FDA's current hands-off regulatory approach does not in any want preclude the agency's authority to adopt a different regulatory scheme in which FDA would actively enforce the statutory listing requirements." (8) Discussion of *American Bioscience* (8), *Watson* (9), and *Mylan* (9). "FDA should use this rulemaking to adopt an effective enforcement scheme for determining whether submitted patents in fact claim the drug or a method of using the drug for which the NDA was submitted." (9)
- Teva agrees with and supports the spirit of the 30-month proposal, but "cannot support this aspect of the proposed rule as written," because it will not prevent abuses. First, "the proposed rule does not provide a mechanism for ANDA applicants to prelitigate patents that are not the first to be listed and challenged for a particular drug." (12) This could be remedied if ANDA applicants had the option to send paragraph IV notifications and trigger 30-month stays, but even this will leave loopholes unaddressed. (11, 12) Second, "where the initial or only patent(s) are improperly listed, there is no mechanism to challenge their listing, and ANDA sponsors will be unnecessarily forced to file a paragraph IV certification and notification and potentially face an improper 30-month stay." (13) Finally, "where the initial patent is properly listed, valid, and dominating (e.g., a valid patent claiming the approved form of the drug substance), such that the ANDA applicant must submit a paragraph III certification, the NDA sponsor would retain a free hand to

challenge their listing, and ANDA sponsors will be unnecessarily forced to file a paragraph IV certification and notification and potentially face an improper 30-month stay." (13) Finally, "where the initial patent is properly listed, valid, and dominating (e.g., a valid patent claiming the approved form of the drug substance), such that the ANDA applicant must submit a paragraph III certification, the NDA sponsor would retain a free hand to

improperly delay generic approval" (13) (*ed note: i.e., by listing a patent later that required a paragraph IV certification).*

- FDA should make it clear that "generic applicants are allowed to voluntarily provide optional paragraph IV notifications for a second (or subsequent) listed patent, which may result in additional 30-month stay or stays." (13) Nevertheless, "the proposal could [already] be interpreted to allow such voluntary subsequent notifications." (13)
- "[I]f the proposed rule did not allow optional notifications, ANDA sponsors might not be able to bring declaratory judgment actions to seek a pre-approval judicial decision in those cases in which the patent holder does not sue, because the statute restricts the courts' jurisdiction to decide declaratory judgment actions brought under an ANDA until 45 days after service of a paragraph IV notification." (14)
- Judicial challenge to the rule is a strong possibility (11) and the proposal does not obviate the need for legislative reform to address other problems inherent in the system. (12)
- Teva supports legislative elimination of the 30-month stay altogether and replacement with a specialized preliminary injunction standard that would allow NDA sponsors "to seek protection of their patents pending resolution of the paragraph IV patent litigation, but that would not *automatically* give a 30-month windfall exclusivity . . . ." Alternatively, Teva supports legislation that would allow a stay only for patents listed within 30 days of initial NDA approval and that would bar future enforcement of a patent against an ANDA holder if the patent owner does not promptly list the patent in the Orange Book and bring a paragraph IV infringement action within 45 days of the ANDA applicant's paragraph IV notification. (14)
- Teva also supports legislation that would establish 180-day exclusivity period forfeiture provisions to prevent exclusivity holders from delaying another generic product's launch. (15)
- If FDA does not implement a regulatory mechanism for review of patents, FDA should support legislation that would provide for meaningful enforcement of the listing requirement. (16)
- Also, FDA should support legislation "to confirm and codify the agency's longstanding bioequivalence regulations." (15)
- Finally, FDA should "either establish a regulatory system, or support legislation that would reform the supplemental exclusivity system (i.e., mandate preservation of appropriate verbiage in reference drug labeling to permit a carve out of protected information), and/or specifically codify FDA's longstanding policy that exclusivity is unavailable for safety-related labeling changes. (15)

36. <u>Washington Legal Foundation</u>

mandate preservation of appropriate verbiage in reference drug labeling to permit a carve out of protected information), and/or specifically codify FDA's longstanding policy that exclusivity is unavailable for safety-related labeling changes. (15)

36. <u>Washington Legal Foundation</u>

- Key points: addresses only the 30-month stay provision: supports FDA's goal and believes FDA is correct that it has the statutory authority to implement the goal; believes FDA's new statutory interpretation is "nonsense" and proposes a different way of achieving the same goal.
- "WLF agrees with FDA . . . that pioneer drug companies have on occasion improperly delayed entry of generic competition by invoking existing regulations to obtain multiple 30-month stays in the granting of ANDAs. WLF also agrees with FDA that it possesses statutory authority to adopt a rule stating that the 30-month stay may be invoked only once in connection with any ANDA. WLF nonetheless disagrees with portions of FDA's statutory analysis and believes that FDA lacks authority to adopt proposed 21 C.F.R. § 314.95(a)(3)." (1)
- "If a pioneer manufacturer decides not to file an infringement action with respect to one patent for which a Paragraph IV certification has been filed, it should not thereby forfeit its right to seek a 30-month stay with respect to later patents that are issued before the ANDA is approved." (2)
- "WLF opposes any efforts by FDA to rewrite the compromise worked out by Congress." (3)
- WLF agrees that FDA "has a plausible basis for interpreting the Hatch-Waxman Act as limiting pioneer manufacturers to a single 30-month stay." However, FDA's reliance on § 355(j)(2)(B)(iii) (and the "amend to include" language) is "wholly implausible." (7) "[T]he word 'include' does not mean (as FDA suggests it means) 'add an item that is not the first of its kind.'" (9, n2)
- FDA should rely on § 355(j)(5)(B)(iii), which states that FDA approval of an ANDA containing a paragraph IV certification shall be made effective immediately unless "an" action is brought for patent infringement within 45 days, in which case approval shall be effective no later than the expiration date of "the" 30-month period following receipt of "the" notice of certification provided by the ANDA applicant. (7-8). Congress's use of the singular indicates the provision was intended to allow no more than one stay in connection with a single ANDA. (8)
- Thus, the rule should be amended to make clear that "whenever a pioneer manufacturer first files a patent infringement suit in response to a paragraph IV certification and does so within 45 days of notification, the 30-month stay on issuance of the ANDA begins to run from the date on which the manufacturer received notice of the certification giving rise to the initial filing of the suit." (12)

of the suit." (12)

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October 31, 2002

Summary of FDA's Proposed Hatch-Waxman Regulations

On October 24, FDA published in the Federal Register proposed changes to its Hatch-Waxman regulations with respect to Orange Book patent listings and 30-month stays. This memorandum summarizes the proposal.

Patent Listings. FDA regulations already provide that drug substance, drug product, and method-of-use patents may be listed. FDA proposes to confirm that the following also may be listed: product-by-process patents (which are product patents) and drug substance patents claiming a different form of the active ingredient (such as a different polymorph) if the form claimed in the patent is regarded as "the same as" the NDA-approved form for ANDA filing purposes. FDA proposes to amend its regulations to provide that the following may not be listed: patents claiming packaging, metabolites, intermediates, and unapproved uses.

Patent Declarations. FDA proposes to require innovator companies to complete a new patent declaration which tracks the substantive patent listing requirements in checklist form. It would also require that the innovator identify by number the specific patent claims that support the listing as a drug substance, product, or method-of-use patent. The specific approved use in the labeling that supports listing of a use patent would also need to be identified.

30-Month Stay. FDA proposes a new approach to 30-month stays. A 30-month stay would apply to any patent for which a paragraph IV certification was made in the original ANDA. It would also be available if an ANDA that did not contain a paragraph IV certification were amended later to include one. A stay would not be available, however, if the original ANDA included a paragraph IV certification to one patent and the ANDA were later amended to include a new paragraph IV certification to a different patent.

Revised
January 31, 2003

COMMENTS ON FDA'S PROPOSED HATCH-WAXMAN REGULATIONS EXECUTIVE SUMMARY

1. **aaiPharma:** FDA's current and proposed regulations fail to ensure that patent owners who are not also the NDA holder receive the rights provided to them by the statute. Opposes 30-month proposal; argues FDA must take steps to ensure NDA holders submit all (and only) listable patents.

2. **AARP:** the final regulation should state explicitly that only one stay per drug product per ANDA is permitted; there should be a time after NDA approval after which the NDA holders should not be able to sue for patent infringement; legislation is necessary.

3. **Academy of Managed Care Pharmacy (AMCP):** applauds the proposal; however, believes legislation is necessary; supports total elimination of 30-month stay.

4. **Alfred Engelberg:** the proposal on 30-month stays will not accomplish its purpose of eliminating abuse of the 30-month rule and it is unlawful; a lawful and effective alternative would be for FDA to recognize that ANDA applicants are never required to amend their ANDAs to include new patent certifications.

5. **Agvar Chemicals:** supports S. 812 and generally opposes the FDA notice because it would not solve the problems with Hatch-Waxman and may distract from legislative efforts; different polymorphs and waters of hydration should not be listable; FDA should not permit listing of product-by-process patents for an active ingredient or formulation if there is already a listed patent that purportedly claims the active/formulation approved in the NDA; the new declaration requirements should apply to patents already listed in the Orange Book; FDA should accept paragraph (viii) statements from ANDA applicants for patents on unapproved uses; legislation is needed to deal with the 30-month stay issue and 180-day exclusivity problems, and to provide a mechanism for generics to challenge listings.

6. **American Pharmaceutical Association (APhA):** supportive of FDA proposal; seeks clarification regarding method of use patents.

7. **American Society of Consultant Pharmacists:** generally supportive of FDA's effort; believes the S. 812 approach to 30-month stays should be used; also comments on federal reimbursement policies that are beyond the scope of the rulemaking. Good language on value of newer medicines for older patients.

8. **American Association of Health Plans:** short letter fully supportive of the proposal; no changes recommended.

comments on federal reimbursement policies that are beyond the scope of the rulemaking. Good language on value of newer medicines for older patients.

8. **American Association of Health Plans:** short letter fully supportive of the proposal; no changes recommended.

9. **Apotex Corp.:** opposes patent listing provision as too expansive; agrees with goal of one 30-month stay but has numerous concerns about interpretation and application of FDA approach; offers several alternate approaches; wants FDA to address 180-day exclusivity issues as well.

10. **Barr Laboratories:** endorses GPhA comments; writes separately (a 2-page letter) to highlight "interim" solution to the 30-month stay issue, which is to give ANDA applicants the option to file a second notice letter; endorses combined regulatory and legislative approach.

11. **Blue Cross Blue Shield Association:** BCBSA supports the goals of the proposed rule and wants it finalized with changes, but also supports legislation.

12. **Blue Cross Blue Shield of Michigan:** supports 30-month stay proposal and listing proposal; has additional suggestions for the final regulation and for legislation.

13. **Business for Affordable Medicine (BAM):** applauds the proposal, supports limit of one 30-month stay but says stay should only apply to patents listed before ANDA submission, wants FDA to establish a procedure for review of Orange Book listings and for delisting, believes legislation is still necessary.

14. **Care:** email message; supportive of FDA proposal.

15. **Caterpillar, Eastman Kodak, and General Motors:** supports the proposed rule, with modifications. Innovators should be required to recertify currently listed Orange Books with the new declaration (modified as recommended); FDA should develop the expertise to oversee the patent listing process; the new 30-month stay rule could lead to further delays (but this coalition still supports it); patents for unapproved uses that do not require clinical trial data should be added to the inventory of patents that may not be listed.

16. **Coalition for a Competitive Pharmaceutical Market (CCPM):** Proposal helps, but is not enough to close all loopholes; need to ensure timely resolution of patent disputes; if this can't be done by FDA, CCPM supports legislation.

17. **Consumers Union (CU) & Consumer Federation of America (CFA):** recommends legislation to wholly eliminate 30-month stay; supports Leahy bill; agrees with FDA on packaging, metabolite, and intermediate patents; disagrees on polymorph and product-by-process patents; opposes FDA proposal on 30-month stay for same reasons as GPhA (no certainty for generic applicants on subsequent-listed patents).

18. **David Eichenauer:** one paragraph letter; agrees with 30-month proposal.

19. **Families USA:** supports clarification on types of patents that may be listed but opposes inclusion of product-by-process and polymorph patents; calls the proposed patent certification a "good step" but insufficient without FDA review

listed patents).

18. **David Eichenauer:** one paragraph letter; agrees with 30-month proposal.

19. **Families USA:** supports clarification on types of patents that may be listed but opposes inclusion of product-by-process and polymorph patents; calls the proposed patent certification a "good step" but insufficient without FDA review

of listability; supports the proposed 30-month stay limitation "in principle" but has same concern as GPhA that it will in some cases eliminate the mechanism for timely resolution of patent disputes.

20. **Federal Trade Commission:** FTC supports the 30-month stay proposal and does not argue for legislation; FTC opposes proposal to allow listing of polymorph and product-by-process patents.

21. **Fish and Richardson:** FDA should await the outcome of Warner Lambert v. Apotex and Allergan v. Alcon, in the Federal Circuit.

22. **Food Marketing Institute:** not a detailed response to the proposal, mostly a discussion of FMI's interest (FMI's retail members operate in-store pharmacies) and the need for reform; supported legislation last year (presumably S. 812); supportive of the proposed rule; believes additional legislative reform is necessary.

23. **Generic Pharmaceutical Association (GPhA):** GPhA opposes the 30-month stay proposal on the ground that brand companies would delay filing infringement cases without the opportunity for a new stay; comprehensive legislative reform along the lines of S. 812 is needed.

24. **GlaxoSmithKline:** GSK generally endorses the FDA proposal, including with respect to listability of patents and the 30-month stay; however: GSK objects to FDA's characterizations of the representations it made in connection with the Paxil listing; FDA's statement that different forms of the active ingredient than found in the marketed product is not a change in policy; there is no reason why a good faith patent listing should estop the patent holder from objecting to ANDA eligibility or advocating that additional data be presented for a determination of sameness; claim-by-claim listing is not appropriate or consistent with the statute; patents covering devices or containers that are integral parts of the drug delivery system; the new regulation should apply only prospectively to NDAs and patents filed after the regulation's effective date.

25. **Greenblum & Bernstein:** FDA should ground its 30-month stay proposal in a different theory (that certification on late listed patents is not an act of patent infringement); a stay should not be available in suits on claims that the NDA holder has not represented to cover the approved product; the patent declaration requirement should apply to all patents already in the Orange Book; and legislation is still needed to eliminate 30-month stays and give generics a mechanism to delist patents.

26. **Johnson & Johnson:** endorses PhRMA comments; writes separately to add thoughts on FDA's proposed changes vis-à-vis the 30-month stay rule, the content of paragraph IV certification notices, and patent listing declaration requirements.

27. **Kos Pharmaceuticals:** disagrees with FDA's proposal to eliminate multiple 30-month stays; proposal's provisions on patent listing are sufficient to prevent

mechanism to delist patents.

26. **Johnson & Johnson:** endorses PhRMA comments; writes separately to add thoughts on FDA's proposed changes vis-à-vis the 30-month stay rule, the content of paragraph IV certification notices, and patent listing declaration requirements.

27. **Kos Pharmaceuticals:** disagrees with FDA's proposal to eliminate multiple 30-month stays; proposal's provisions on patent listing are sufficient to prevent

improper listing; proposed new interpretation of statute is plainly incorrect; elimination of stay will prejudice patent holders; little evidence that elimination of stay will result in greater availability of generic drugs

28. **Michigan for Affordable Pharmaceuticals:** These comments are identical to the comments of Blue Cross Blue Shield of Michigan (see # 12).

29. **Mylan Pharmaceuticals:** supports the proposal (except the 30-month provision) subject to some caveats, also supports legislative reform along the lines of S. 812. Proposes additional changes relating to 180-day exclusivity (use of court of appeals decision as exclusivity trigger) and 30 day listing deadline (withdraw NDA).

30. **National Association of Chain Drug Stores (NACDS):** more of an explanatory piece, comparing S 812 and the proposed rule; prefers S 812 approach to use of deadlines for patent listing and patent infringement suits; 180-day exclusivity issues need to be addressed and until Congress does so, FDA should permit rollover; FDA should clarify its role in reviewing patent listings; and ANDA applicants should be able to challenge improper listings.

31. **New York State Department of Public Health:** "enthusiastically" supports the proposal; offers no criticism.

32. **Organon:** opposes the proposal; FDA should withdraw the Proposed Rule or, at a minimum, (1) clarify that certain use patents are eligible for listing without regard to whether they claim an approved use, and (2) continue its longstanding policy of imposing a stay on ANDA approval whenever the ANDA (or an amendment to the ANDA) contains a paragraph IV certification.

33. **Pfizer:** questions need for reform on 30-month issue; reserves judgment on whether FDA's revisions are legally appropriate; FDA should allow listing of patents that claim packaging and containers the agency would require prior approval for any changes in those elements; endorses PhRMA comments and concerns about generic manipulation of new interpretation of stay provision; FDA should provide notice to NDA holders for subsequent paragraph IV notifications; FDA should re-issue proposed rule for a second round of comments.

34. **Rx Health Value** (Verizon, GM, Ford, BCBS, etc.): questions value of any 30-month stay; agrees that one 30-month stay is appropriate alternative; believes there should also be mechanisms to force rapid resolution of patent disputes, along the lines of S. 812; innovators would not be prejudiced by immediate implementation; Administration should support legislation in light of widespread questioning of FDA's statutory authority

35. **Teva:** supportive of FDA effort but finds it doesn't go far enough; recommends a number of modifications and insists legislative reform is still needed. For example, opposes listing of polymorphs. Believes FDA's listing proposal could be read to allow NDA holders to list buffers, antioxidants and preservatives not

implementation; Administration should support legislation in light of widespread questioning of FDA's statutory authority

35. **Teva:** supportive of FDA effort but finds it doesn't go far enough; recommends a number of modifications and insists legislative reform is still needed. For example, opposes listing of polymorphs. Believes FDA's listing proposal could be read to allow NDA holders to list buffers, antioxidants and preservatives not

used in the Reference Listed Drug. FDA should give more examples of nonlistable patents. Patent declarations should be made public when the NDA is approved. The agency should adopt a mechanism for reviewing listability and for delisting patents. FDA should adopt the listing declaration questions proposed by GPhA. Teva cannot support the 30-month proposal, because it doesn't give ANDA applicants a way to litigate subsequent-listed patents prior to market entry. FDA should make it clear that generic applicants may voluntarily provide optional notices and trigger stays. Various legislative reforms also required (including on 180-day exclusivity).

36. **Washington Legal Foundation:** addresses only the 30-month stay provision: supports FDA's goal and believes FDA is correct that it has the statutory authority to implement the goal; believes FDA's new statutory interpretation is "nonsense" and proposes a different way of achieving the same goal

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Draft
January 8, 2003

Generic Industry Flip-Flop

	THEN	NOW (Comments to FDA in Hatch Waxman Rulemaking, 12/23/2002)
Whether Hatch-Wa	**Whether Hatch-Waxman Limits Innovators to ONE 30-Month Stay**	
YES. "FDA should make c authorizes one 30-m Pharmaceutical Asso the Hatch-Waxman A "The Agency . . . doe the 30-month stay pr making clear that the more than one 30-m Pharmaceutical Asso the Hatch-Waxman A "Once FDA approve has expired, the Age is non-discretionary a Pharmaceutical Asso the Hatch-Waxman A "Congress did not int	**YES.** "FDA should make clear that the Hatch-Waxman Act only authorizes one 30-month stay per ANDA." Generic Pharmaceutical Association Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p8) "The Agency . . . does have the authority to address the abuses of the 30-month stay provisions by brand-name companies by making clear that the Hatch-Waxman Act does not authorize more than one 30-month stay per ANDA." Generic Pharmaceutical Association Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p15) "Once FDA approves an ANDA, and once a single 30-month stay has expired, the Agency's task of making that approval effective is non-discretionary and purely ministerial." Generic Pharmaceutical Association Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p15) "Congress did not intend for more than one 30-month stay to	**NO.** "FDA's proposal to limit brand companies to a single 30-month stay per ANDA could, however, cause further imbalance in the Hatch-Waxman system by impeding the ability of generic companies to obtain timely resolution of legitimate patent disputes." (p3) "The 30-month stay functions as the principle incentive for brand companies to participate in the expedited Hatch-Waxman process. . . . Partial removal of that incentive, as proposed by the FDA, without the addition either of new incentives or public policy mandates requiring brand companies to list patents in the Orange Book and to initiate timely litigation on those patents, will encourage brand companies to act later, rather than sooner, to protect their patents." (p4) "As long as 30-month stays remain available to brand companies (even if only one such stay is available per ANDA, as FDA proposes), these companies will have an incentive to list patents on the eve of generic competition, regardless of whether the

	THEN	NOW (Comments to FDA in Hatch Waxman Rulemaking, 12/23/2002)
delay marketing of a only a single 30-mon decision to play a pu Generic Pharmaceuti Symposium on the H "GPhA urges FDA t intent that an ANDA *single* 30-month stay and comprehensive d Generic Pharmaceuti Symposium on the H "FDA should make c authorizes one 30-m Pharmaceutical Asso the Hatch-Waxman / "[T]he language, leg Waxman Act all clea one 30-month stay t Pharmaceutical Asso Symposium on the H "In short, the Hatch- purpose make clear t ANDA." Generic Ph to FDA, Symposium	delay marketing of a generic drug. The importance of permitting only a single 30-month stay is further supported by FDA's decision to play a purely ministerial role in listing patents." Generic Pharmaceutical Association Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p16) "GPhA urges FDA to give effect to Congress' clearly expressed intent that an ANDA be made effective after the expiration of a *single* 30-month stay. . . . It is essential that FDA provide clear and comprehensive direction on this important question." Generic Pharmaceutical Association Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p18) "FDA should make clear that the Hatch-Waxman Act only authorizes one 30-month stay per ANDA." Generic Pharmaceutical Association Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p34) "[T]he language, legislative history, and purposes of the Hatch-Waxman Act all clearly establish[] that Congress intended only one 30-month stay to apply for each ANDA." Generic Pharmaceutical Association Reply Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p16) "In short, the Hatch-Waxman Act's legislative history and purpose make clear that there can only be one 30-month stay per ANDA." Generic Pharmaceutical Association Reply Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p17)	patent meets the stautory/regulatory criteria." (p22) "[M]easures to limit abuse of the Hatch Waxman system need not undercut provisions to ensure that brand companies list eligible patents in the Orange Book and initiate early litigation against ANDA applicants with Paragraph IV certifications. FDA's effort to solve the problem of gaming of the 30-month provisions suffers from precisely this flaw and in the end may actually undermine the ability of generic companies to resolve patent disputes as early as possible." (p30)

"GAAP achives signi current laws that allo generic drug approva more affordable medi GAAP . . . include lir month automatic stay testimony of Kathlee Commerce, Subcomr	"GAAP achives significant savings by closing loopholes in the current laws that allow brand name drug companies to block generic drug approval and thereby delay consumers' access to more affordable medicine . . . The significant provisions of GAAP . . . include limiting brand drug companies to a single 30-month automatic stay of generic drug approvals." (Written testimony of Kathleen Jaeger, House Committee on Energy and Commerce, Subcommittee on Health, 10/19/2002)	
Whether the Gener	**Whether the Generic Industry Needs Orange Book Listings to Learn of Innovator Patents**	
YES "GAAP achives signi current laws that allo generic drug approva more affordable medi GAAP [include] prov name drugs . . . The p essential to providing (Written testimony o Energy and Commer "An Orange Book lis companies with notic either owns or licens Pharmaceutical Asso the Hatch-Waxman A	**YES** "GAAP achives significant savings by closing loopholes in the current laws that allow brand name drug companies to block generic drug approval and thereby delay consumers' access to more affordable medicine . . . The significant provisions of GAAP [include] providing an accurate list of patents for brand name drugs . . . The proper listing of all relevant patents is essential to providing timely access to affordable medicine." (Written testimony of Kathleen Jaeger, House Committee on Energy and Commerce, Subcommittee on Health, 10/19/2002) "An Orange Book listing is intended to provide generic drug companies with notice of the patents that the brand company either owns or licenses that claims the relevant NDA." Generic Pharmaceutical Association Submission to FDA, Symposium on the Hatch-Waxman Act (1/30/02) (p10)	**NO** "[G]eneric companies regularly conduct comprehensive due diligence efforts to assess corporate liability and market opportunities. Corporate patent due diligence efforts consist of, among other things, the identification and assessment of patent [sic] issued by Patent & Tradement Office (PTO) as well as patent application spending before that agency." (pp19-20, and 20, n13) "For example, generic companies perform due diligence investigations to identify patents either issued by the Patent and Trademark Office ('PTO') or pending before PTO that may affect their interests. 35 U.SC. § 122 provides for pre-approval publication of patent applications 18 months after the earliest filing date, thereby enabling generic companies and other interested parties to review a patent application's contents before the patent is issued by PTO." (p20, n14)

	THEN	NOW (Comments to FDA in Hatch Waxman Rulemaking, 12/23/2002)
		"Any minimal benefit provided by such notice ["the notice function of the Orange Book"], if one exists at all, is far outweighed by the opportunity that such a change in policy [allowing polymorph patents to be listed] would give brand-name companies to artificially obtain a 30-month stay by listing a late-filed patent that must be litigated before the generic product may be marketed." (p20)

January 7, 2003

Brief Summary of PhRMA Comments
On FDA's Proposed Hatch-Waxman Regulations

On December 23rd, PhRMA submitted comments to FDA on the agency's proposed new regulations implementing the patent listing and 30-month stay provisions of the Hatch-Waxman Amendments. The key points in PhRMA's comments follow.

1. The proposed regulations would make significant changes to current law.

   - Since 1984, NDA and patent holders have had the opportunity to obtain a 30-month stay on FDA approval of an abbreviated new drug application or 505(b)(2) application whenever the applicant makes a paragraph IV certification challenging a listed patent. The proposed rule would eliminate this opportunity in certain circumstances.
   - FDA's proposal would also make several categories of patent ineligible for listing in the Orange Book.
   - FDA's proposal would also significantly expand the information that an NDA sponsor must include in the patent declaration it submits with its NDA.

2. PhRMA's comments do not take issue with FDA's authority to limit innovator companies to one 30-month stay, assuming that that the technical issues described below are adequately addressed.

3. FDA must address a loophole in its proposal, to ensure that the new regulation provides innovators with a meaningful opportunity for a 30-month stay on approval of an ANDA or 505(b)(2) application.

   - FDA's stated intent is to ensure that innovator companies always have a meaningful opportunity for one 30-month stay on approval of an ANDA or 505(b)(2) application.
   - FDA's proposal is rooted in the concern that NDA holders should not be able to obtain multiple stays when litigation is brought on newly issued and listed patents.
   - FDA does not address the situation when an ANDA or 505(b)(2) applicant amends its patent certification of its own accord. In this situation, FDA's proposal could deny the innovator a meaningful opportunity for a stay. For example, an applicant could submit its ANDA with a paragraph III certification on a drug substance patent and a paragraph IV certification on a narrow formulation patent. The innovator might determine that the formulation does not infringe and might therefore choose not to sue. If the generic applicant subsequently amends its paragraph III certification on the substance patent to a

proposal could deny the innovator a meaningful opportunity for a stay. For example, an applicant could submit its ANDA with a paragraph III certification on a drug substance patent and a paragraph IV certification on a narrow formulation patent. The innovator might determine that the formulation does not infringe and might therefore choose not to sue. If the generic applicant subsequently amends its paragraph III certification on the substance patent to a

paragraph IV certification, under FDA's theory the innovator would receive no notice and no stay would apply.

- FDA should therefore provide that an amendment to an ANDA or 505(b)(2) application that is made to change an existing patent certification (that is, one filed with the original application) relates back to, and substitutes for, the original patent certification. It would therefore trigger the notice requirement, and the innovator could obtain a stay.
- This solution addresses the loophole that PhRMA has identified. It also better furthers FDA's stated intent, while continuing to address – in the same way as FDA's proposal – FDA's concern about newly listed patents.

4. ANDA and 505(b)(2) applicants should be required to provide notice to the NDA or patent holder when they change the formulation of a product that is the subject of a pending application. Otherwise, if the applicant files a paragraph IV certification to a non-infringing formulation and later amends its application to use a formulation that does infringe, the NDA or patent holder would have no meaningful opportunity for a stay.

5. FDA should post paragraph IV certifications on its website or otherwise make them public. This will ensure that NDA and patent holders learn of those certifications and are able to enforce their intellectual property rights, even when notice is not required under FDA's new interpretation of the statute.

6. FDA should clarify in its preamble that patents claiming a form of a drug substance that is the "same" as the active ingredient in the NDA (for example, a polymorph) have always been listable. FDA's proposal to require their listing is a reasonable reading of the statute and is consistent with prior agency policy.

7. FDA does not need to elaborate the listing criteria for product-by-process patents. These patents are product patents, and the listing criteria used for other product patents should be used.

8. FDA proposes to require that NDA sponsors submit detailed information about each claim in the patent declarations submitted with their NDAs. This is improper. Under the statute, patents – not claims – are submitted to FDA for listing, and ANDA and 505(b)(2) applicants provide certifications as to patents rather than claims.

9. For drug substance claims, FDA proposes to require NDA sponsors to state whether the claim covers an active ingredient that is "the same" as the active ingredient in a NDA. If so, the sponsor would be required to acknowledge that an ANDA or 505(b)(2) application containing the same active ingredient is also "the same" for ANDA or 505(b)(2) approval purposes. This is improper. Determination of sameness for purposes of ANDA approval is FDA's responsibility. NDA sponsors should at most be required to acknowledge that FDA has indicated an ANDA containing the form of the active ingredient may be the same as the reference listed drug for approval purposes.

505(b)(2) application containing the same active ingredient is also "the same" for ANDA or 505(b)(2) approval purposes. This is improper. Determination of sameness for purposes of ANDA approval is FDA's responsibility. NDA sponsors should at most be required to acknowledge that FDA has indicated an ANDA containing the form of the active ingredient may be the same as the reference listed drug for approval purposes.

January 21, 2003

Federal Trade Commission Comments: Consumers Will "Benefit Significantly" from FDA Proposal: Legislation Not Needed

Last summer, the Federal Trade Commission released a comprehensive study that described industry practices that it believed delay FDA approval of generic drug products. Although the FTC included legislative recommendations to addresses the possibility of further delays, the Administration opted to proceed instead through regulations. On October 24, FDA released proposed new regulations implementing the patent listing and 30-month stay provisions of the Hatch-Waxman Amendments. On December 23, the FTC submitted its comments on this proposal. The FTC's comments make clear that it has concluded the regulatory approach will address its concerns. Legislation is not required.

FDA's proposal regarding 30-month stays is an "important reform" and an "effective way" to facilitate generic market entry. One of the "chief" recommendations in last summer's FTC Study "was a proposed limitation of only one automatic 30-month stay per drug product per abbreviated new drug application" (page 2 of FTC comments). The FTC had "included legislative recommendations" to address this issue (2). According to the FTC's December filing, the FDA proposal "although not identical to the FTC Study's recommendation, is an important reform that would eliminate a substantial portion of the potential for unwarranted delay of FDA approval of generic drugs identified by the FTC study" (2). "Consumers should benefit significantly" (2). Notably, the FTC no longer recommends legislation. It writes that "the FDA proposal is an effective way to bring cheaper, generic copies of brand-name drug products to the market" (7).

In short, last summer, the FTC recommended legislation to address its concerns about generic market entry under Hatch-Waxman. FDA has demonstrated, to the FTC's apparent satisfaction, that a regulatory approach is adequate.

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From: "Baran, Denise" <dbaran@sherwood-group.com>
To: "'njl@browdyneimark.com'" <njl@browdyneimark.com>
Date: Thu, Jan 23, 2003 2:08 PM
Subject: AUTM Annual Meeting - Last Day to Preregister!

TO: Norman J. Latker, JD, Browdy & Neimark
MEMBER ID: 06670

Just a reminder that today is the last day that you can pre-register for the 2003 Annual Meeting in Orlando, Feb. 6-8, 2003. After today, you will need to register on site at a higher rate.

To register online at the reduced member rate, you will need your member ID which is listed at the beginning of this e-mail. Register online at: http://www.autm.net/store/2003Annual/regnotice.cfm

Along with the many great networking opportunities and educational sessions, you'll want to take note of the following events.

Prize Drawing for Disney Tickets!
Complimentary one-day passes to any Disney theme park will be awarded at the Annual Business Meeting, Friday, Feb. 7. You must be present to win!

Pleasure Island Tickets
Join your friends for an optional night out at Pleasure Island in Downtown Disney. Discounted tickets are available to AUTM attendees for $20 per person. The ticket price includes private motor coach transportation to Downtown Disney from 7 p.m. until 9 p.m. as well as admission to Pleasure Island. Disney provides complimentary shuttle service back to the Contemporary Resort. Purchase your tickets when you register for the meeting. Additional tickets may be available on site at the meeting.

Golf at Lake Buena Vista Golf Course
Space is still available for the AUTM golf outing at Lake Buena Vista Golf Course. The course is located just ten minutes from the Contemporary Resort. Buses will leave from the hotel at 12:15 p.m. Registration for this event is $150 and includes lunch, transportation to and from the golf course, green fees and cart rentals. Prizes will be awarded at the closing dinner.

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This e-mail broadcast has been sent to all members of AUTM. If you prefer not to receive periodic updates from AUTM via e-mail, please contact autm@autm.net.

From: "Queen, Cynthia" <Cynthia.Queen@dbr.com>
To: "'cohn@warf.ws'" <cohn@warf.ws>, "'richard_turman@aau.edu'" <richard_turman@aau.edu>, "'njl@browdyneimark.com'" <njl@browdyneimark.com>
Date: Fri, Jan 17, 2003 11:59 AM
Subject: RE: Next informal working lunch of representatives of theunivers ity/non-profit community and the pharmaceutical industry

Please see the attached email as sent yesterday. Unfortunately, we had wrong email addresses for you. Thanks, Cindy

> -----Original Message-----
> From: Queen, Cynthia On Behalf Of Remington, Michael J.
> Sent: Thursday, January 16, 2003 5:04 PM
> To: 'rhardy@cogr.edu'; 'cohn@warf.com'; 'richard_turman@aau.com';
> 'rharpel@nasulgc.org'; 'sheinig@aamc.org'; 'njl@browdyniemark.com';
> 'vvolpe@phrma.org'; 'jkelly@phrma.org'
> Cc: 'sheldon_steinbach@ace.nche.edu'; Wilson, Christopher E.
> Subject: RE: Next informal working lunch of representatives of the
> university/non-profit community and the pharmaceutical industry
>
>
> The restaurant chosen is available on both days. Please email me with
> your preference as we need to finalize as soon as possible. We will then
> choose a date convenient for all. Thanks, Cindy Queen
>
> -----Original Message-----
> From: Remington, Michael J.
> Sent: Wednesday, January 15, 2003 6:43 PM
> To: 'kphillips@cogr.edu'; 'rhardy@cogr.edu'; 'cohn@warf.com';
> 'richard_turman@aau.com'; 'rharpel@nasulgc.org'; 'sheinig@aamc.org';
> 'njl@browdyniemark.com'; 'vvolpe@phrma.org'; 'jkelly@phrma.org'
> Cc: 'sheldon_steinbach@ace.nche.edu'; Wilson, Christopher E.; Queen,
> Cynthia
> Subject: Next informal working lunch of representatives of the
> university/non-profit community and the pharmaceutical industry
>
> Dear all:
>
> We would like to hold a second informal luncheon meeting of
> representatives of the university/non-profit community and the
> pharmaceutical industry on either February 27, 2003, or February 28, 2003.
> The meeting will be hosted by Shelley Steinbach at a site to be
> determined.
>
> At this point in time, I would merely request that you hold in reserve
> these two days until reservations can be made somewhere in the downtown DC
> area.
>
> Since our initial meeting on September 28, 2002, new developments have
> arisen and new issues raised. For example, talk is occurring on Capitol
> Hill about oversight hearings on the Bayh-Dole Act (the pressure for the
> hearings is coming from Bayh-Dole opponents). International patent issues
> have moved again to the front burner in the latest round of negotiations
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From: Sheridan Neimark
To: All
Date: Sun, Jan 19, 2003 5:58 PM
Subject: Jan 2003 Scientific American

Whover has this issue, I need it.
SN

OPINION

Innovation's golden goose

Dec 12th 2002
From The Economist print edition

The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

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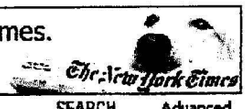

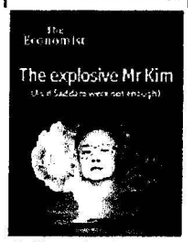

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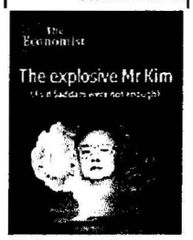

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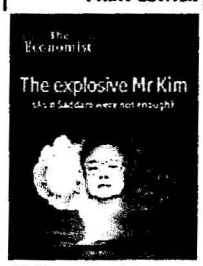

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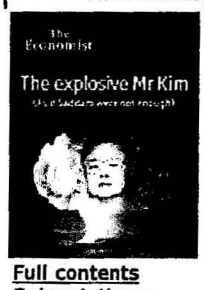

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Dec 12th 2002
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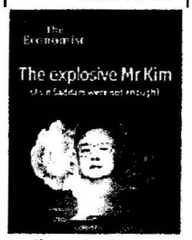

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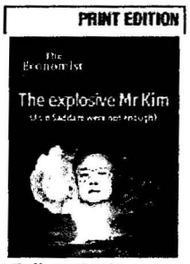

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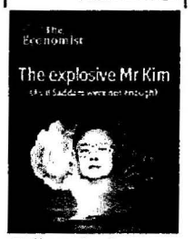

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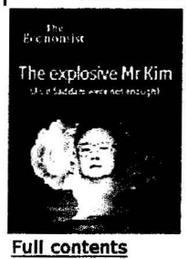

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That is easily answered. Invention, as *TQ* has stressed before, is in many ways the easy bit. A dollar's worth of academic invention or discovery requires upwards of $10,000 of private capital to bring to market. Far from getting a free lunch, companies that license ideas from universities wind up paying over 99% of the innovation's final cost.

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Whatever the merits of their case, suffice it to say that the sole purpose of the Bayh-Dole legislation was to provide incentives for academic researchers to exploit their ideas. The culture of competitiveness created in the process explains why America is, once again, pre-eminent in technology. A goose that lays such golden eggs needs nurturing, protecting and even cloning, not plucking for the pot. Readers who agree or disagree can share their own views at www.economist.com/forums/tq.

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OPINION

Innovation's golden goose

Dec 12th 2002
From The Economist print edition

The reforms that unleashed American innovation in the 1980s, and were emulated widely around the world, are under attack at home

REMEMBER the technological malaise that befell America in the late 1970s? Japan was busy snuffing out Pittsburgh's steel mills, driving Detroit off the road, and beginning its assault on Silicon Valley. Only a decade later, things were very different. Japanese industry was in retreat. An exhausted Soviet empire threw in the towel. Europe sat up and started investing heavily in America. Why the sudden reversal of fortunes? Across America, there had been a flowering of innovation unlike anything seen before.

Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act of 1980. Together with amendments in 1984 and augmentation in 1986, this unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money. More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.

Before Bayh-Dole, the fruits of research supported by government agencies had belonged strictly to the federal government. Nobody could exploit such research without tedious negotiations with the federal agency concerned. Worse, companies found it nigh impossible to acquire exclusive rights to a government-owned patent. And without that, few firms were willing to invest millions more of their own money to turn a raw research idea into a marketable product.

The result was that inventions and discoveries made in American universities, teaching hospitals, national laboratories and non-profit institutions sat in warehouses gathering dust. Of the 28,000 patents that the American government owned in 1980, fewer than 5% had been licensed to industry. Although taxpayers were footing the bill for 60% of all academic research, they were getting hardly anything in return.

The Bayh-Dole act did two big things at a stroke. It transferred ownership of an invention or discovery from the government agency that had helped to pay for it to the academic institution that had carried out the actual research. And it ensured that the researchers involved got a piece of the action.

Overnight, universities across America became hotbeds of

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From: Niels Reimers <niels@stanford.edu>
To: <njl@browdyneimark.com>
Date: Sat, Feb 22, 2003 5:40 PM
Subject: Bayh-Dole challenge

Hi Norm,

I wanted to thank you (belatedly) for sending the Economist article on "Innovation's Golden Goose". As it turns out, I also subscribe to the Economist and made note of it as well. I think I will leave it to those "on active duty" to deal with the challenge, although I suspect both of us would lend our help if asked. I talked with Howard in connection with a case he is expert witnessing and for which I was asked to provide supporting information. I have avoided expert witnessing because I would want freedom to be completely candid, rather than as an advocate for one side or another.

I am impressed that you are still working.....at least your letterhead is still Browdy & Neimark! Actually, I have been working as well, doing consulting and the income has been very welcome right now as we are building a house here in Carmel and just whether our cash flow will be adequate after it is completed is yet to be learned.

Have you been making your periodic pilgrimages to England? I was to give a talk at The Hague in December but asthma laid me low and I had to cancel. Then a couple more growing-old things, including double vision, which has put my golf on hold. But my health is getting better and I'll be heading off to Japan for 11 days next month, visiting medical schools in the west and south of Japan.

Take care,
Niels

From: Robin Rasor <robinlr@umich.edu>
To: <njl@browdyneimark.com>
Date: Tue, Feb 18, 2003 1:20 PM
Subject: 30th anniversary of AUTM

I don□t believe we ever met, but I am the VP Planning for the AUTM Board of Trustees and the annual meeting falls under my purview. We will be celebrating the 30th anniversary of the founding of AUTM at next years annual meeting in San Antonio March 4-6. I am in the process of finding and inviting the original 7 (now 6) founders as well as you, Howard Bremer and Joe Allen. AUTM would pick up your travel expenses, etc. As we get closer, we□ll be planning the exact festivities, but I wanted to get in contact with you to see if you would block it on your calendar.

Please let me know what address I should use to send a formal invitation. I look forward to meeting you in Texas!

Robin L. Rasor
Director of Licensing
The University of Michigan
3003 S. State Street, Suite 2071
Ann Arbor, MI 48109-1280
(734)615-8433; FAX (734)936-1330
robinlr@umich.edu

From: "Remington, Michael J." <Michael.Remington@dbr.com>
To: "'njl@browdyneimark.com'" <njl@browdyneimark.com>
Date: Wed, Jan 15, 2003 7:05 PM
Subject: FW: Message Delivery Failure

Norm,

Second try. Sorry.

Mike

-----Original Message-----
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Thank you very much

€□□
Dear all:

We would like to hold a second informal luncheon meeting of representatives of the university/non-profit community and the pharmaceutical industry on either February 27, 2003, or February 28, 2003. The meeting will be hosted by Shelley Steinbach at a site to be determined.

At this point in time, I would merely request that you hold in reserve these two days until reservations can be made somewhere in the downtown DC area.

Since our initial meeting on September 28, 2002, new developments have arisen and new issues raised. For example, talk is occurring on Capitol Hill about oversight hearings on the Bayh-Dole Act (the pressure for the hearings is coming from Bayh-Dole opponents). International patent issues have moved again to the front burner in the latest round of negotiations on the Doha Declaration on TRIPS and public health. And, there is growing concern about judicial movements to create a common law research exemption in the patent law. I mention these three items not to control the agenda but merely to stimulate your thinking about what should be discussed and what lies ahead. Your views about agenda items will be solicited. And an agenda will be approved in advance.

As you know, the group previously reached an informal consensus (which I communicated to you on September 30, 2002) on several items including a birthday party for the Bayh-Dole Act on December 12, 2003, a grass roots approach to Bayh-Dole programs to occur at universities/non-profits where successful collaborative research and technology transfer have occurred, and the overall need to avoid reductions in patent protection not only domestically but worldwide. As regards the first item, some advance planning should be contemplated. As regards the second, assuming that we proceed, we should think about a site to host a regional conference on the Bayh-Dole Act. That site should not only be a success story but should attract key political representatives. Because the Bayh-Dole Act created a profession of technology transfer, perhaps its 23rd birthday should be celebrated in the field. Again, these thoughts are set forth to stimulate your own and to assist in setting a framework for a successful second meeting.

Best regards,

Mike

Thank you very much

º□

Thank you very much

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Name : BROWDY AND NEIMARK

Job number : 276
Date : Oct-07 11:40am
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Document pages : 013
Start time : Oct-07 11:40am
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SENT TO: Carl / Barbara

DATE SENT: 10/7/02

SUBJECT: Buyh-Dole

No. of pages (including this cover sheet):

FROM: Norm Latker

Remarks:

Carl / Barbara
Carole and I enjoyed our conversation with you last Night. I thought this brief overview of the evolution of Buyh-Dole from 1964 to date might be of interest to both of you (and possibly Dr. Lienhart since it is part of NIH's history).
(ignored)
Regards
Norm L.

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SENT TO: Mike Remington

DATE SENT: 10/7/02

SUBJECT: Bayh-Dole committee

No. of pages (including this cover sheet): 13

FROM: Noam Latker

Remarks: Mike

I thought this brief overview of the evolution of Bayh-Dole from 1964 to date might be of interest to you (and possibly the committee if you consider that appropriate).

Note the similarity of Dr. Shawnow's 1964 testimony before Congress and Gary Glover's presentation.

Regards
Noam L.

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Date	:	Mar-11 01:43pm
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TELEFAX CONTROL SHEET

SENT TO: Jennifer Washburn

DATE SENT: 3/11/03

SUBJECT: Tech. Trans

No. of pages (including this cover sheet):

FROM: Norm Latker

Remarks: Jennifer
Enclosed are the Science article I mentioned and my C.V.
I'm enclosing the C.V. since it highlights most of the policy, regulatory and legislative actions that comprise the body of law governing federal technology transfer. Also you might find something of interest in the list of presentations I made over time, most of which are not easily found. NJZ

"time", most of which are not easily found. NJZ

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Time : Mar-10-2003 03:00pm
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To	:	17188323568
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Start time	:	Mar-10 02:52pm
End time	:	Mar-10 02:59pm
Pages sent	:	012
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Job number : 509 *** SEND SUCCESSFUL ***

1ST Slide

HIGHLIGHTS Of FEDERAL TECHNOLOGY TRANSFER

- 1964 - DHEW inventions not reaching the marketplace.
- 1968 -Disputes over Federally funded inventions
- 1968 - G.A.O. Report.
- 1969 - DHEW patent policy changed.
- 1973 - First technology transfer Association formed
- 1976 - First gene splicing patent licensed

- 1976 - First gene splicing patent licensed

WASH. POST

Merrill Goozner

Prescription For Reform

The prescription drug benefit sections of the Medicare legislation just passed by Congress do nothing to rein in the rising cost of pharmaceuticals or to foster innovation in the drug industry.

In fact, it will probably make a bad situation worse.

A 2001 Nobel Prize went to three economists who explained how unequal access to information distorts a marketplace and robs consumers. The only solution to the "imperfect information" problem is for government to either set prices or pass prudent regulations aimed at correcting mistaken purchases by poorly informed consumers. A good example of the latter is automobile lemon laws.

Under current regulations, no marketplace is more prone to the problem of unbalanced information than pharmaceuticals. As the late U.S. senator Estes Kefauver (D-Tenn.) put it while investigating drug industry price-fixing in the early 1960s, he who prescribes does not buy and he who buys does not prescribe. Combine that with the fact that neither the drug purchaser—whether it be patients or their insurance companies—nor the prescriber—the physician—has very good information about the best and most cost-effective use of most drugs, and you have a prescription for price gouging.

The root cause of this information deficit can be found in the nation's system for studying and approving drugs, whether they are supposedly innovative molecules seeking government approval for the first time or older medicines that have been around for years. The FDA rarely requires the pharmaceutical industry to conduct those tests.

The result is that both the public and the medical profession receive a skewed analysis of the relative worth of various medicines.

Yes, a new drug is safe.

Yes, it is somewhat efficacious against the targeted disease; no drug is universally effective, and many drugs help only a small portion of the people who take them. But how does it stack up against those already on the market?

Only in rare cases does the industry engage in comparison trials, since the risk of losing—and getting totally shut out of a market—is too great.

It is much easier to develop new drugs to replace those coming off patent and then push the latest (and therefore more expensive) offerings by spending vast an army of salespersons, enrolling physicians in semi-scientific "testing" trials whose real purpose is to expose their patients to the new

Only comprehensive comparative trials, conducted by a neutral third party, can provide that kind of objective information.

On the rare occasion of such trials, they have generated surprising results.

For instance, last winter, the National Institutes of Health released the results of its decade-long $50 million test of competing blood pressure control medicines.

It showed that diuretics, so-called water pills that have been around since the 1950s and can be purchased for pennies a day, were slightly more effective than the still-on-patent calcium channel blockers and ACE (angiotensin converting enzyme) inhibitors.

This is not to say that the newer drugs aren't the right choice for many patients, or that elderly Americans who need more than one drug to keep their blood pressure under control shouldn't have access to them. But, with $15 billion being poured into blood pressure medicines every year, the study's authors believed the nation's health care system could save billions by starting most patients off with diuretics.

Two easy reforms would rectify this information deficit.

First, the government could empower NIH or an independent agency to conduct systematic comparative trials on all classes of medicines with multiple entries. The results of those trials would provide physicians with authoritative clinical practice guides to the best and most cost-effective medicines.

Second, the FDA's drug approval process could be amended to include comparative clinical trials for any new drug that a company wants to bring to the market.

The industry will complain that the additional clinical testing would drive up the cost of approving new drugs and choke off innovation.

But just the opposite would occur. The pharmaceutical industry currently spends more than 60 percent of its $34 billion research and development budget on clinical trials.

But much of that money is wasted on trials designed to benefit the marketing arms of the companies and winds up generating more noise than useful information for practicing physicians.

A new requirement that drug companies test their latest offerings against existing medicines would force them to focus their R&D budgets on truly innovative medicines and help identify the best uses for existing drugs.

Merrill Goozner, a Washington-based writer, is author of the forthcoming book "The $800 Million Pill: The True Cost of New Drugs."

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"The $800 Million Pill: The True Cost of New Drugs."

[NI]H Braces for Slower Funding Growth

[Presid]ent May Apply Brakes on 14% to 15% Annual Increase and Trim It to 2%

[By ... We]iss
[Washington] Post Staff Writer

[With] hours left before President [Bush] lifts the veil from his [budge]t request, the National [Institutes o]f Health is bracing for a [cas]e of whiplash.

[W]hat it's going to feel [like], [experts] said, as the nation's [lea]der of biomedical re[search end]s its five-year run of 14 [to] 15 percent annual fund[ing increases] and hits the wall of a 2 [percent inc]rease, which sources in[side and ou]tside the government [say ha]s settled upon.

[The ripp]les from that impact [will touch t]ens of thousands of sci[entists who] depend on NIH grants, [they sai]d, and over time could [make a dif]ference to millions of [patients] who are counting on [them to] deliver new treatments [... s]ide.

"Two or three years of 2 or 3 percent increases, and you've pretty much lost what you've gained," said Dave Moore, associate vice president at the Association of American Medical Colleges. "And you've certainly lost the morale of investigators who can't help but be demoralized by trying to compete for funding under those circumstances."

That threat has inspired some on Capitol Hill to call for granting the agency a budget growth of at least 8.5 percent annually over the next three years, which would result in a tripling of the NIH budget between 1999 and 2008.

The NIH is by far the largest federal grant-giving agency for the biomedical sciences. Its 27 institutes and centers support 50,000 primary investigators and countless other laboratory workers at more than 2,000 institutions. The Bethesda campus itself is home to dozens of major research labs, to the National Library of Medicine, which operates the world's largest online database of scientific journals, and to a teaching clinical research center that admits 7,000 patients a year and coordinates outpatient studies involving another 72,000 participants.

Congress has often voted for more funding for the NIH than the president requests. This year, however, the pressure to hold spending growth nearly flat is greater than ever.

Administration officials have done their best to put a positive light on the proposed 2 percent increase. They note that if $1.4 billion in unique bioterrorism-related expenditures in 2003 are not counted—including the one-time funding of new biodefense research buildings and a $250 million purchase of anthrax vaccine—then the 2004 budget request would represent a 7.5 percent increase over the 2003 budget, assuming Congress settles on about $27 billion for 2003.

In a less extreme ... [illegible] ... officials have calculated that the 2 percent increase for 2004 ... 4.6 percent increase ... [illegible] ... but not lost under the current economic circumstances, said NIH's Popple.

"We all knew at the time that the five-year doubling was ... and it would end at five years," Popple said. "And there will be lots of spin-offs" for medicine, he said, from the new spending on bioterrorism.

But others dismissed those calculations as "spin." For example, some noted, although the bioterrorism building and infrastructure costs for 2003 are high, the need for new construction is ongoing.

"We've doubled the size of the enterprise, but we have a lot of people working in buildings that are 30 or 40 years old," said Patrick White of the Federation of American Societies for Experimental Biology (FASEB), which is recommending a 10 percent increase in NIH funding for 2004. "We can't just stop paying attention to infrastructure."

Although the dollar amount of nonbioterrorism research would increase marginally under the president's proposal, the number of nonbioterrorism grants in 2004 would decline to 9,487, down from 9,724 this year. By contrast, the number of bioterrorism-related grants is set to nearly double to 601, from this year's 358.

Daniel E. Smith, national vice president for government relations at the American Cancer Society, said it would be a mistake to trim growth at a time when advances in molecular biology are finally offering cancer patients higher survival rates and a better quality of life.

"We see the money tha[t goes] into NIH as a little like Mir[acle-Gro] for cancer research, and [if we] don't finish the doubling [it will st]unt the growth of the re[search]," Smith said. With cancer [costing] the nation more than $60 b[illion in] medical expenses and mo[re than] $171 billion in related co[sts, the] cancer institute's roughly [$4.6 bil]lion budget is a bargain[, he] said.

Sens. Arlen Specter (R-[Pa.] and) Tom Harkin (D-Iowa) rec[ently in]troduced a resolution to t[riple the] NIH budget during the dec[ade end]ing in 2008. Now, with the [release of] the president's budget be[ing near,] advocates for research are [gear]ing for battle.

"We're very grateful to [the ad]ministration and the A[merican] people for their investment [in NIH] and biomedical research, bu[t this is] not the time to be penurio[us and re]strictive," said FASEB Pr[esident] Steven L. Teitelbaum. "This [is not a] subsidy, but an investme[nt, and I] hope we can convince the a[dminis]tration and Congress that [this is] the wisest investment th[ey can] make."

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Packard Foundation Will Get $2 Billion Gift From Founder

Continued From Page A1

ning in third world countries.

Reflecting Mr. Packard's interest, there will be a $10 million fellowship program for young professors in engineering and science to encourage them to remain in research and teaching.

The foundation will also contribute substantially to the Monterey Bay Area Research Institute, which is undertaking deep underwater exploration using unmanned vehicles, another area of interest to Mr. Packard.

$20 Million Program

There also will be a $20 million support program for education, family and youth problems. Some of these projects, still being developed, include child care, employment training, grants to black colleges and to programs to curb drug abuse and teen-age pregnancy. Programs in conservation and the arts will be expanded.

Mr. Packard now divides his time between the foundation and his office at Hewlett-Packard, where he spends two days a week.

He speaks without a trace of nostalgia about his term from 1969 to 1971 as Deputy Defense Secretary in the Nixon Administration. Although he returns to Washington on occasion and two years ago headed a Presidential commission studying military spending, he suggested the experience only reinforced his convictions about the frustrations of working within Government as compared with the freedom for meaningful activity he finds outside.

The foundation's future course was mapped at a time when his wife was in failing health and he was recuperating after surgery.

"We spent a lot of time together formulating plans we hope will characterize what the foundation will do," he said. "I have observed that money left without special guidance is sometimes used well and sometimes not. We decided we would both work on it."

Philanthropy of Children

The emerging program reflects their shared aim to accommodate the interests of their children. Like the Rockefeller family, the Packard children were introduced early to philanthropy and took their places on the foundation board as young adults.

The foundation finances a number of projects in the ancient studies [illegible] areas of interest to their son David W. Packard, a classics scholar [illegible] Latin, Greek, Coptic and Hebrew.

Two of the Packard daughters, Nancy Packard Burnett and Julie E. Packard, have graduate degrees in marine biology. Julie heads the Monterey Bay Aquarium, an institution with a high reputation that was built by the Packards from their personal wealth.

Another daughter, Susan Packard Orr, has a degree in the computer sciences and a background in administration. She has been developing software packages that will help nonprofit organizations track their fund-raising and grant-making activities and thereby improve efficiency.

The Packards hold five of the eight places on the foundation's board. The others are occupied by Dr. Robert J. Glaser, a physician who is [illegible] director of the Lucille Markey [illegible] tion in Florida, Frank Roberts [illegible] yer, and Edwin E. Van Bronkhorst [illegible]

Giving It Away: The Wealthiest Foundations

Assets in 1987. The David and Lucile Packard Foundation [illegible] receive $2 billion over the next few years [illegible]

Ford Foundation, New York	$4,758,862,000
J. Paul Getty Trust, California	[illegible]
W. K. Kellogg Foundation, Michigan	3,106,323,350
MacArthur Foundation, Illinois	[illegible]
Lilly Endowment Inc., Indiana	1,913,868,091
Robert Wood Johnson [illegible]	[illegible]
Rockefeller Foundation, New York	1,605,[illegible]
[illegible]	[illegible]
Andrew W. Mellon Foundation, New York	1,477,000,000
[illegible]	[illegible]

It will be one of the six richest U.S. foundations.

[illegible] former vice president of Hewlett-Packard.

Day-to-day management is supervised by the foundation's executive director, Colburn S. Wilbur.

Wife's Role in Programs

Threaded through Mr. Packard's remarks on the expansion are frequent references to his wife's contributions. "I cannot remember a year that she was not building something," he said.

Mrs. Packard's concern about the needs of the local community also helped shape her thinking about the planned children's hospital named for her, which will have a close relationship to Stanford Medical School. The Packards contributed $40 million from their personal wealth. The ground breaking was held earlier this month.

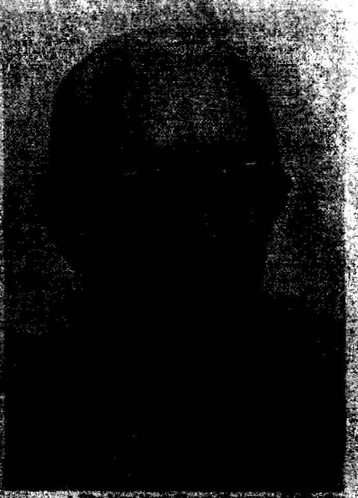
New ideas keep cropping up about areas for action, Mr. Packard said. The foundation receives about 1,600 proposals for its assistance and gives out about 330 grants a year. That will increase.

"We're having some fun doing it all," Mr. Packard said.

ackard Foundation Will Get
$2 Billion Gift From Founder

By KATHLEEN TELTSCH
Special to The New York Times

)S ALTOS, Calif., April 22 — David
tard has decided to give a $2 billion
ine he amassed in the electronics
stry to charitable causes, reflecti
commitment shared with his late
and their four children.
'er the next few years virtually all
tock in the Hewlett-Packard Com
will go to the David and Lucile
tard Foundation, making the
nthropy one of the five or six
thiest in the country. The
ndation is the wealthiest
on.
Ve
vanish
e poli
-old
nterview
Assuming
ng," he
th even
have
hes,
on's
legs with some difficulty beneath a
e too small for his 6-foot-4 frame, he
liscussed his personal fortune and
anthropy.
he foundation, incorporated in 1964,
has assets of $145 million and
kes grants of about $10 million a
r, but Mr. Packard has already
ted to increase its resources sub-
ntially.



David Packard

The foundation's headquarters are a
few miles from Stanford University,
where Mr. Packard and William Hew-
lett met as engineering students and
then, 40 years ago, started their joint
enterprise, scratching together $598
and beginning work in a garage.
Mrs. Packard, who died last May,
was deeply involved in child health con-
cerns, and a substantial share of the
foundation's work will be devoted to
protecting infants and children at high
risk of developing health problems.
The foundation will also have a $10 mil-
lion program in population activites,
particularly supporting family plan-

Continued on Page A18, Column 1

VTIP Home

Technology Transfer in U.S. Research Universities:

Dispelling Common Myths

Preamble

During the past two decades, universities have surprised everyone, including themselves, with the tremendous success in licensing their research results for commercial application. Through "technology transfer" they provide commercial sector companies with access to new discoveries and innovation resulting from research. Industrial partners develop these inventions and manufacture products that help to improve the lives of Americans. However, with success tends to come notoriety, often based on misunderstanding or distortion of facts. News stories of university millionaires tend to catch the eye more effectively than scientific articles about the drugs and devices that would not have become available had university inventions not been successfully commercialized.

This pamphlet addresses commonly held myths about university technology transfer. Some of them are explained by the provisions of the underlying legislation, which not only provides incentives, but also imposes controls to guard the public taxpayer's interests. Some of them are explained by statistics, which deflate the perception that universities derive a steady income stream from technology transfer.

The biggest myth to dispel is that universities engage in technology transfer "for the money". Three factors explain why universities are currently so active in partnering with industry. First, under the Bayh-Dole Act, universities have a mandate to ensure, to the extent possible, that inventions arising from federally funded research are commercialized. It is an obligation they have increasingly embraced since 1980 when the law was enacted. Secondly, universities need to make sure they have adequate resources to enable faculty to continue to do research and to provide learning opportunities for students. And finally, universities must consider their obligation to respond to the needs of local and state economies and the nation as a whole.

This brochure was prepared by the Technology Transfer and Research Ethics Committee of the Council on Governmental Relations (COGR). COGR is an organization which includes in its membership 145 research-intensive universities.

Council on Governmental Relations
1200 New York Avenue NW, Suite 320
Washington, DC 20005
(202) 289-6655

May 2000

Technology Transfer in U.S. Research Universities:

Dispelling Common Myths

Myth: ***The new emphasis on technology transfer is diverting universities from their main mission of***

(202) 289-6655

May 2000

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http://www.vtip.org/myths.htm 11/23/2003

education and research.

Reality: Technology transfer is not a new phenomenon for universities. Dating from the early 1800's in Europe, companies are known to have been developed around the expertise of faculty at universities. Research universities have historically transferred technology through the traditional methods of publication, the training of students, and through their extension programs. Formal technology transfer through the licensing of university-owned intellectual property adds new educational dimensions and research opportunities for students and faculty.

Myth: ***The government is better at commercialization through technology transfer than universities are. Therefore, the government should regain control of university patents that have come from federally-funded research projects***

Reality: The university sector has been highly successful in its technology transfer efforts since it was given the right to own and license university inventions under the Bayh-Dole Act in 1980. Prior to 1980 when university patents were generally owned by the federal government, no more than 10% of those patents were licensed to industry for commercialization. Data for FY98 on university licensing activities show that universities are filing in excess of 4,000 patent applications a year and issuing more than 3,500 licenses or options to license annually.[i] Trend data show a cumulative total of licenses and options issued since 1991 standing at over 20,000 and that the percentage of licensing activity has doubled between 1991 and 1998.[ii] Anecdotal reporting from universities shows a licensing to patenting ratio of better than 1:3. There is a general consensus that licensing is most effective if it directly involves the inventor and the inventor's institution.

Myth: ***University technology transfer is an unnecessary barrier to effective commercialization. More rapid commercialization would be achieved if universities gave their inventions to industry.***

Reality: As owners of their inventions, universities have established procedures for the earliest possible identification of inventions. The patenting and commercialization process benefits from day-to-day communication with inventors, access to complementary technology that may be under development within the university and awareness of continuing efforts on the part of the inventor to enhance a technology. Through licensing, universities ensure diligent efforts toward commercialization by the licensee, or require the license to be returned to the university to be issued to a more serious commercial partner. Universities have both the incentive and the ability to build internal relationships and structure to make certain that rapid and effective commercialization occurs.

Myth: ***Most university patents come from federally-funded research paid for by U.S. taxpayers. Neither the U.S. government nor the taxpayer is benefiting.***

Reality: Recent data and the application of impact models[iii] show a return to the U.S. government and the national economy from university licensing of $33.7 billion, and -supported 280,000 jobs during the university fiscal year ending June 30, 1999. The return to the federal government in taxes paid on university technology transfer induced corporate and individual earnings, alone, equals a 15% return on sales of licensed products.[iv] The public is currently benefiting from the products, processes and services available in the marketplace as a result of more than 17,000 active university licenses.

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