Daniel G. Brown
is a partner in the New York law firm Frommer Lawrence & Haug, LLP, and practises extensively in the Hatch–Waxman area. He has been practising in New York since 1993 in the patent and intellectual property area.

Recent developments in US law: Remedies and damages for improper patent listings in the FDA's Orange Book

Daniel G. Brown

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Abstract

The Drug Price Competition and Patent Term Restoration Act (Publ. No. 98-417, 98 Stat. 1585 (1984)), commonly known as the Hatch–Waxman Act (the Act) provides the statutory framework by which most generic drugs are approved for marketing in the USA. Most provisions in the Act concern the standards and procedures the US Food and Drug Administration (FDA) must follow to approve generic drugs. A relatively small number of the provisions, however, create a framework for resolving patent disputes between the brand and generic pharmaceutical companies. These provisions have been the subject of much recent activity, in the US Courts, in Congress, in the FDA itself and in the White House. Much of the activity revolves around a publication by FDA entitled *Approved Drug Products with Therapeutic Equivalence Evaluations,* known colloquially as the *Orange Book.*

Under present FDA practice, the mere listing of a patent in the Orange Book corresponding to a brand pharmaceutical product invokes a number of statutory provisions that confer valuable exclusivity rights on the brand company, and also possibly on one or more generic companies. This situation creates a strong incentive for patentees and brand pharmaceutical companies to list patents in the Orange Book. A number of recent court cases have addressed the remedies and damages available when the listing is found to be improper. Thus far, the most successful means to challenge or prevent improper listings has been through private and governmental enforcement of the antitrust laws.

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Daniel G. Brown
Frommer Lawrence & Haug LLP,
745 Fifth Avenue,
New York, NY 10151, USA

E-mail: DBrown@flhlaw.com

BACKGROUND

Basic Hatch–Waxman framework

ANDA filing

Pharmaceutical companies may obtain FDA approval to market a drug a number of different ways, but the two most common are through a New Drug Application (NDA) or through an Abbreviated New Drug Application (ANDA). An NDA must contain evidence 'to show whether or not [the] drug is safe for use and whether such drug is effective in use'[1] (emphasis added). This 'safety and efficacy' requirement in an NDA usually requires extensive clinical trials (animal and human) showing that the drug does not have adverse effects and that it is effective in treating the indications for which approval is sought.[2] Once approved, an NDA is eligible for a number of statutory exclusivity periods ranging from five years for a new chemical entity, to three years for less substantial developments. These exclusivity periods are independent of any exclusivity that may be provided by patent protection.

The FDA's ANDA procedure is an abbreviated process through which the FDA will approve certain drugs that are 'bioequivalent' to drugs already FDA-approved via a non-abbreviated NDA.[3] An ANDA applicant does **not** have to submit clinical trial data showing safety and efficacy.[4] Instead, the ANDA applicant relies on the safety and efficacy data for an already-marketed NDA

Hatch-Waxman background

product of another company (called a 'listed drug'), and must show that the ANDA product has the same active ingredient as, and is 'bioequivalent' to, the listed NDA product.[5] Typical evidence used to show an ANDA product is bioequivalent includes dissolution data matching the aqueous dissolution profile of the listed NDA product, and data showing that the blood plasma release rate matches that of the NDA product in a side-by-side bioequivalence study.[6]

The ANDA applicant must also submit information showing (i) the composition of its product (including impurities); and (ii) 'the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug.'[7]

The patent certification requirement, and Orange Book listing

35 USC §271(e)(2) Infringement and the §271(e)(2) Exemption

The Act amended the patent laws to provide that submitting an ANDA can be an act of patent infringement. In particular, 35 USC §271(e)(2) provides that it is an act of patent infringement to submit an ANDA 'for a drug claimed in a patent or the use of which is claimed in a patent.' As characterised by the courts, the filing of an ANDA is a 'technical' or 'artificial' act of infringement that permits the courts to resolve patent infringement disputes based on the filing of an ANDA, rather than waiting for the end of the approval process and the marketing of the generic product.[8] The infringement issue is whether the proposed drug product would, if marketed, infringe.[9]

In addition the act amended the patent laws to exempt from patent infringement acts done solely for purposes reasonably related to submission of information under a Federal law regulating the manufacture and sale of drugs or veterinary biological products. There is also an exemption from the exemption – animal drugs and veterinary biological products made using recombinant technology or genetic manipulation do not qualify for the exemption. One practical effect of this provision was to speed the approval of generic products by allowing the studies necessary for filing an ANDA, and the filing of the ANDA itself, to happen prior to expiration of patents covering the drug. While this effect has received the most attention, there may be a number of additional significant effects. For example, the provision may clear research-based pharmaceutical companies to experiment with and develop compounds that fall within the scope of broad genus patents owned by competitors. Patents for diagnostic or screening methods or products raise additional issues, and it is not clear how the exemption will ultimately be applied to these types of patents.

The statutory basis for the Orange Book and the FDA's interpretation of the effects of filing

Patent certification

The Act requires an NDA holder to submit certain patent information to the FDA. Specifically, the NDA holder is required to submit 'the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the [NDA] or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the commercial manufacture, use or sale of the drug.'[10] The FDA publishes this information in the Orange Book.[11]

Any generic drug manufacturer wishing to file an ANDA relying on that NDA product as the reference listed drug must file with FDA one of four certifications, or for certain patents a 'section viii' statement discussed below. These certifications are as follows:

- that no patent information has been submitted for publication in the Orange Book (a 'Paragraph I certification');
- that the patent in the Orange Book has

The 30 month Hatch-Waxman Stay

expired (a 'Paragraph II certification');

- the expiration date of the Orange Book patent (a Paragraph III certification.') – if the ANDA applicant files a Paragraph III certification, the FDA will not give approval to market the generic product until the expiration date of the patent;

- that the Orange Book Patent is invalid or will not be infringed by the manufacture, use or sale of the ANDA product (a 'Paragraph IV certification).

The Act itself does not directly tie the requirement that the ANDA applicant file these certifications to the listing of the patents in the Orange Book. Instead the Act states that the Paragraph I–IV certifications must be filed 'with respect to each patent which claims the [reference listed drug] or which claims a use for such listed drug for which applicant is seeking approval.'[12] The FDA, however, presently requires these certifications for all Orange Book patents, and will not accept a Paragraph IV certification as to any patent that is not listed in the Orange Book.

Submitting patent information for listing in the Orange Book

If the Orange Book patent is a method-of-use patent that does not claim a use for which the ANDA applicant is seeking approval, the ANDA applicant can file a 'section viii' or 'little eight' statement). A section viii statement is available only for method-of-use patents. If the ANDA applicant does not seek approval for the use claimed in the patent, it can file a section viii statement and is eligible for immediate FDA approval when all other requirements are met. Unlike a paragraph IV certification, a section viii statement does not require the applicant to provide notice to the patentee or NDA holder. A section viii statement is also not subject to the 30 month stay provisions, or to the generic exclusivity provisions of the Act.

Notification and the 30 month Hatch–Waxman stay

If an ANDA applicant files a Paragraph IV certification, it must also send a notice letter to the NDA holder and patent owner that includes a detailed statement of the factual and legal bases of the ANDA applicant's opinion that the patent is invalid or not infringed. If the NDA holder or patent owner sues within a 45 day period after receiving the notice letter, the FDA will automatically withhold approval of the ANDA for 30 months, unless a court shortens this period or renders a final decision that the patent is invalid or not infringed, in which case the FDA may approve the ANDA upon the court's final decision.[13]

Accordingly, the mere listing of a patent in the Orange Book initiates a series of events that can enable a patentee or NDA holder to prevent generic competition for up to 30 months, if it initiates litigation and can maintain the litigation for the 30 month period.

FDA's regulatory framework for submission of patent information for listing in the Orange Book

The listing standard under the FDA's present regulations

The FDA's regulations permit listing only of patents that claim the drug that is the subject of the NDA, or a method of use for that drug that is approved in the NDA or an amendment or supplement to it. Each NDA applicant is required to submit patent information for:

> Each patent that claims the drug or a method of using the drug that is the subject of the new drug application or amendment or supplement to it. And with respect to which a claim of patent infringement could reasonably be asserted. . .. For patents that claim a drug substance or drug product, the applicant shall submit information only on those patents that claim a drug product that is the subject of a pending or approved application, or that claim a drug substance that is a component of such a product. For patents that claim a method of use, the applicant shall submit information only on those

FDA's position is that it acts in a purely ministerial role in listing patents in the Orange Book

patents that claim indications or other conditions of use of a pending or approved application.[14]

But the FDA does not exercise oversight of the patent submission procedure to ensure that these requirements are met. Instead, the FDA presently relies on a declaration from the NDA holder.

The FDA's listing procedures

For a patent to be listed in the Orange Book, the NDA holder must submit information that primarily includes (1) the number and expiration date of the patent; (2) the type of patent, ie drug, drug product, or method of use; (3) the name of the patent owner. The NDA holder must also submit a declaration in the following form:[15]

> The undersigned declares that Patent No. ____ covers the formulation, composition, and/or method of use of *(name of drug product)*. This product is (currently approved under section 505 of the Federal Food, Drug, and Cosmetics Act) [or] (the subject of this application for which approval is being sought):
>
> _____

FDA's regulatory procedure for challenging Orange Book listings

The NDA holder must submit the patent information and the signed declaration. If the patent owner is different from the NDA holder, the FDA will not accept patent information directly from the patentee, but only from the NDA holder.[16]

The patentee who is not the holder of an NDA will typically fall into one of three categories: (1) a subsidiary or affiliate of the NDA holder; (2) a third party that has licensed its patent to the NDA holder; or (3) a third party who is not connected with the NDA holder but who contends that its patent should be listed in the Orange Book. The first two situations do not typically present any particular complications if the patent meets the listing requirements. The NDA holder is generally willing to list the patent, and submits the patent information on behalf of the patentee.

The third situation has resulted in recent litigation, however. In one recent case, *aaiPharma, Inc. v Thompson*, a patentee sued the FDA, contending that the patentee should be permitted to directly list its patent in the Orange Book without the assent of the NDA holder.[17] The FDA argued in response that its role in listing the patent information was 'purely ministerial', and that it would accept the information only from the NDA holder as provided in the regulations. The US Court of Appeals for the Fourth Circuit rejected the patentee's contention. The Court explained that it was clear that the patentee had no remedy against the NDA holder for refusing to submit the patent to the FDA for listing.[18] The court then held that the FDA's position was not 'arbitrary and capricious' and that it could continue to apply a purely ministerial approach to Orange Book listing.[19]

The FDA's regulatory procedure for challenging Orange Book listing

The FDA's regulations contain a nominal procedure for challenging Orange Book listing. It consists of three steps:

- Any person who disputes the correctness of the patent listing must 'notify [FDA] in writing stating the grounds for disagreement.
- The FDA will then 'request of the new drug application holder that the correctness of the patent information be confirmed'.
- 'Unless the [NDA] holder withdraws or amends its patent information in response to FDA's request, the agency will not change the patent information in the list.'

The *aaiPharma* Court characterised the FDA's procedure as follows: 'if the NDA holder stands on its Orange Book listing, aggrieved parties are out of luck.'

Using the Administrative Procedure Act to challenge Orange Book listings in court

The incentive to submit patents for listing in the Orange Book

The automatic 30 month Waxman–Hatch stay of generic approvals, creates an obvious incentive for NDA holders (and others) to submit patents for listing in the Orange Book. Indeed, submission is required by the statute for patents that meet the statutory and regulatory requirements for listing. Many drug products account for several million dollars per day in revenues at monopoly prices, but only a small fraction of that when generic competition sets in. It is not unusual for a 30 month delay in generic competition to be worth in excess of a billion dollars to the NDA holder.

When the patent meets the statutory requirements for listing, and the ensuing litigation is well grounded in fact, the delay period represents the legislative bargain envisioned in the Act. The FDA's refusal to police Orange Book listings, however, has led to situations in which patents have been improperly submitted for listing. This has in turn led to a number of different strategies to challenge the listing procedures by those affected.

RECENT EFFORTS TO CHALLENGE ORANGE BOOK LISTING

Initial efforts to bring an Administrative Procedure Act case for delisting were successful

ANDA applicants have recently tried a number of different ways to challenge Orange Book listings: delisting suits against the FDA, delisting suits against the NDA holder, antitrust suits against the NDA holder, and actions against the FDA to require it to accept a 'section viii' statement. The first two have been largely unsuccessful thus far, although the contours have not yet been fully worked out. The third, antitrust litigation, has met with success in some cases. Recent cases have also clarified the availability of a section viii statement, which for method-of-use patents allows an ANDA applicant to avoid the paragraph IV procedures entirely.

Action against the FDA under the Administrative Procedure Act: *Watson v Henney*

In one recent case, a generic manufacturer sued FDA under the Administrative Procedure Act (APA) to challenge the listing of a patent in the Orange Book for the product buspirone. *Watson Pharmaceuticals, Inc. v Henney,* Civil No. 00-3516 (D.Md. 2001). The suit arose when the NDA holder submitted a patent relating to a metabolite of buspirone for listing in the Orange Book. The listing occurred on the final day of the patent exclusivity period arising from the patent on buspirone itself. The filing of the patent in the Orange Book suspended approval of ANDAs that were to be approved the following day.

One of the ANDA holders sued the FDA in the US District Court for the District of Maryland. The ANDA holder argued that the FDA acted in an arbitrary and capricious manner in refusing to approve the generic drug based on an improperly listed patent. The ANDA holder argued that the Orange Book patent did not cover the NDA-approved drug, which was covered by an expired patent. The FDA argued in response that it had followed all of its procedures in listing the patent. In particular, it had required the NDA holder to submit a declaration that the patent covered the NDA product, and upon challenge from the ANDA holder had required the NDA holder to confirm the correctness of the information. The FDA maintained that it had no obligation to independently review the correctness of the patent submission.

The district court ruled that the FDA's listing decision was not arbitrary and capricious:

> 'So long as the FDA is acting within the scope of law and regulation, which it did here when it accepts the patentee's declaration, the Court had no warrant to second guess it. The FDA's action here under attack was not unreasonable, arbitrary, or

Filing a declaratory judgment action against the patent owner/NDA holder to delist the patent

capricious, but was rather, a reasonable exercise of its statutory and regulatory powers.'

The court indicated however that the listing dispute could be settled by private litigation between the NDA holder and ANDA holder. This case was eventually dismissed on appeal as moot.[20]

Action against the patent owner/NDA holder: *Mylan v Thompson and Bristol Myers Squibb Co.*

Initial efforts to delist patents by suing the patent owner/NDA holder were successful

A second attack on the listing of the buspirone metabolite patent was brought by another generic company directly against the NDA holder to compel the delisting of the patent. This approach was successful in the district court, and resulted in the delisting of the patent. The US Court of Appeals for the Federal Circuit reversed however, again on grounds that did not reach the merits of the listing itself.

In this case, Mylan brought a declaratory judgment action seeking to compel Bristol Myers Squibb to delist the buspirone metabolite patent on the grounds that it did not claim the approved NDA product buspirone. The district court agreed with Mylan and entered an injunction requiring Bristol to request the FDA to delist the patent.

Antitrust action for delisting

On appeal, the Federal Circuit concluded that Mylan's declaratory judgment claim was 'in essence an attempt to assert a private right of action for 'delisting' under the [Federal Food Drug and Cosmetics Act]' (the FFDCA). Since the FFDCA in most circumstances does not allow for private enforcement, the Court held that Mylan's claim for delisting was barred by the statute. The Court noted, however, its determination in a previous case that courts did have jurisdiction to order delisting 'in the context of a properly filed patent infringement suit'. The Court found that the precedent did not provide authority for it to hear an independent case for delisting outside a properly filed patent case. Because it found that Mylan's declaratory judgment action was not available under the patent laws or the Hatch–Waxman Act, the court declined to consider the merits of the Orange Book listing.

Antitrust action against NDA holder – *In re Buspirone*

A third approach tried in the buspirone matter was to directly sue the NDA holder under the antitrust laws. Watson and Mylan each sued Bristol to recover the damages from the delay caused by the Orange Book listing and subsequent 30 month stay. A number of other parties also sued Bristol, including at least 29 state attorneys general, and a number of class action groups. The cases were consolidated in the US District Court for the Southern District of New York.

Antitrust liability in the USA can arise through private litigation, actions by state governments, or enforcement by the Federal government. A defendant found liable for violating the antitrust laws can be required to pay damages, which may be trebled, and injunctions or other sanctions are also possible.

The district court in *In re Buspirone* made an important ruling concerning the viability of the antitrust laws as a remedy for improper Orange Book listings.[21] Early in the case, Bristol made a motion to dismiss the antitrust suit under the *Noerr-Pennington* doctrine. The *Noerr-Pennington* doctrine – too complex for a complete discussion here – provides a limited immunity from suit for activities related to petitioning the government. The right to petition the government for redress is guaranteed under the First Amendment to the US Constitution. Under certain circumstances, the Noerr-Pennington Doctrine can provide a party with immunity for its activities in petitioning the government, which can include the bringing of a lawsuit. Bristol contended that its submission of the metabolite patent for listing in the Orange Book, and subsequent patent infringement suits were protected under

this doctrine, immunising it from antitrust liability.

Orange Book listing held not to qualify for antitrust immunity under the Noerr-Pennington doctrine

The court rejected Bristol's argument and held that the submission of patent information to the FDA for listing in the Orange Book was not 'petitioning' under the First Amendment, and thus not entitled to immunity. The court noted the FDA's policy of treating listing as a purely ministerial act, and found that the submission of patent information for listing was not petitioning because it was not an effort to influence government decision making:

> 'The Noerr-Pennington doctrine is not applicable to conduct through which private parties seek to achieve anticompetitive aims by making representations to the government in circumstances where the government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations.'

Filing section viii statement for method of use patents

The court went on to hold that even if the listing of the patent in the Orange Book were 'petitioning' activity, Bristol was still not entitled to immunity because the listing and subsequent litigation to obtain the 30 month stay were 'objectively baseless', in part because Bristol sought to reclaim subject matter that entered the public domain when its original patents on buspirone expired:

> Bristol-Myers has taken the straightforward position that it can, in effect, extend a monopoly and reclaim an invention after the expiration of its patent on the invention, when [i]t is self-evident that on the expiration of a patent the monopoly created by it ceases to exist, and the right to make the thing formerly covered by the patent becomes public property.

In contrast to this ruling, in another decision from the Southern District of New York, the court rejected an antitrust action alleging improper Orange Book listing.[22] The court based its decision on Noerr-Pennington immunity, and distinguished the buspirone case in part on the ground that the patentee listed the patents in question and initiated litigation during the term of the original patent covering the drug product.

In addition to private litigation under the antitrust laws, the US Federal Trade Commission has become more involved in asserting the antitrust laws on behalf of the USA in matters involving improper Orange Book listings.[23]

Section viii litigation – *Purepac v Thompson*; *Warner Lambert v Apotex*

Two recent cases have addressed the availability of a section viii statement – also known as a statement of inapplicable use – as an alternative to a paragraph IV certification. Both cases arose out of litigation concerning the epilepsy drug gabapentin. In *Purepac Pharmaceutical Co v Thompson*, one generic manufacturer, Purepac, sued the FDA to require it to accept a section viii statement for one of four Orange Book patents listed with respect to gabapentin.[24] Purepac filed a paragraph III certification with respect to one of the patents, and was the first to file a paragraph IV certification with respect to two of the patents.[25] The fourth patent (the '479 patent) claimed the use of gabapentin to treat neurodegenerative diseases. Gabapentin was not FDA-approved for neurodegenerative diseases, however. Its only approved use was for treatment of epilepsy, which is not a neurodegenerative disease. Purepac filed a section viii statement with respect to the '479 patent.[26]

Another ANDA applicant, Apotex, filed a paragraph IV certification with respect to the '479 patent. FDA refused to approve Purepac's ANDA with a section viii statement for this patent, but instead issued a requirement that Purepac file a Paragraph IV certification.[27] Purepac refused on the ground that the patent claimed an off-label use, and that a section viii statement was the appropriate

The Purepac Court rejected FDA's refusal to accept a section viii statement

response to the patent.[28] The FDA argued that the dispute centred around the scope of the patent and that such disputes could be resolved only in private litigation between the parties, not by the FDA which acts only in a ministerial role in listing patents. In response Purepac sued the FDA for approval of its ANDA.[29]

The US District Court for the District of Columbia held that the FDA's refusal to approve Purepac's ANDA with a section viii statement rather than a paragraph IV certification was arbitrary and capricious.[30] The court characterised the FDA's position as a syllogism: (i) the FDA permits the listing of patents only for approved uses of an NDA product; (ii) the only explanation for Warner-Lambert's decision to submit the '479 patent for listing is that the patent must claim an approved use of gabapentin; (iii) the only approved use of gabapentin is for treatment of epilepsy; (iv) therefore the '479 patent claims the use of treating epilepsy, making a paragraph IV certification necessary.[31] The court rejected the FDA's logic:

Warner-Lambert court held that there is no cause of action against generic applicants for off-label use

> 'This version of the argument fails, however, for its premise is fictitious. At bottom, the FDA regulations categorizing the types of patents that are to be listed in the Orange Book are hortatory, not definitional. That is, they do no more than tell patent owners what patents they may lawfully submit for publication. Thus, while the regulations tell those parties what they are *supposed* to do, they do not keep non-conforming patents, submitted in violation of the rules, out of the Orange Book.'
> . . .
> [FDA's] theory makes sense only if it were impossible for a brand manufacturer to break the agency's rules. But this assumption is belied by the FDA's own approach to policing Orange Book submissions. Indeed, the agency's much-touted 'purely ministerial' role in the publication process, along with its policy of deferring to the representations of NDA holders about the scope of their patents, make it entirely possible that a brand manufacturer could submit a patent for publication (and see it published) without believing or averring that it actually covered an approved use.[32])

After considering the evidence in the administrative record, the court held that the FDA's refusal to approve the Purepac's ANDA with a section viii statement for the '479 patent was arbitrary and capricious.

In a related action, *Warner Lambert Co v Apotex Corp.*, 2003 WL 124307 (Fed. Cir., 16th January, 2003) the US Court of Appeals for the Federal Circuit held that the Hatch–Waxman Act did not create a cause of action for patent infringement for method-of-use patents for off-label uses. The Federal Circuit affirmed the grant of summary judgment by the district court, addressing Apotex's paragraph IV certification for the '479 patent at issue above in the *Purepac* case. The Federal Circuit confirmed that 'a certification [under paragraphs I–IV] need not be provided for a patent claiming a use for which the ANDA applicant is not seeking approval, ie a use not covered by the NDA.'[33] Apotex's paragraph IV certification for the '479 patent 'was effectively a statement of inapplicable use pursuant to [section viii].' Because the '479 patent did not claim an approved use, the Court held that 'Warner-Lambert does not have a cause of action under § 271(e)(2)(A)', the Hatch–Waxman patent infringement provisions. Accordingly, the court affirmed the grant of summary judgment that Apotex's ANDA did not infringe the '479 patent.

While many details remain to be worked out, these cases indicate the viability of a section viii statement for ANDA applicants to address method-of-use patents.

McCain-Schumer proposes to change Orange Book listing procedures

LEGISLATIVE AND REGULATORY EFFORTS: THE MCCAIN–SCHUMER LEGISLATION AND FDA PROPOSED REGULATION

The recent controversy surrounding improper Orange Book listings has resulted in legislative activity to amend Hatch–Waxman. The most significant responses to date have been the McCain–Schumer bill, 107 S. 812 (2002), and a proposed regulation from the FDA. Any law that may ultimately issue as a direct or indirect result of the McCain–Schumer bill will likely be the result of a good deal of further legislative negotiation. Nonetheless, certain of its provisions may affect the Orange Book listing issue:

- A single 30 month stay would apply only with respect to patents that were issued at the time the NDA was approved. This would reduce the incentive for NDA holders to file patents that issue later since the stay would not apply.
- The NDA holder would be required to provide more detail as to how the patent covers the NDA product or use and would be required to file a more detailed declaration affirming this.
- ANDA holders would have specific authority to challenge the listing of certain Orange Book patents.

FDA's proposed regulations

The FDA's proposed regulation is likewise subject to potential change before going into effect. It is presently in a public comment period that ended on 23rd December, 2002. Some of its current provisions would also affect the Orange Book listing issue:

- The regulation would specify that metabolite and intermediate patents are not listable.
- The regulation confirms that method-of-use patents must claim a pending or approved application.
- The regulation would permit listing of hydrate and polymorph patents.
- The regulation would require a detailed declaration requiring the NDA holder to specify which claims of the submitted patent covers the approved or pending NDA product or approved use of the drug and answer specific 'Yes or No' questions concerning the listing.
- The regulation would permit only one 30 month stay.

CONCLUSION

Orange Book listing and its associated effects are certain to be the subject of continued activity by the Courts, the FDA and Congress. In view of the significant effects and benefits that flow from the mere listing of a patent, it is important that the process be limited to those patents that meet the statutory standards laid out by Congress.

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