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January 15, 2002

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

Dear Sir or Madam:

## Citizen Petition Expedited Decision Requested

On behalf of Baker Norton Pharmaceuticals, Inc. ("BNP"),<sup>1</sup> the undersigned submits this petition under 21 U.S.C. § 355(j)<sup>2</sup> and 21 C.F.R. §§ 10.25(a) and 10.30. Courtesy copies of this petition are simultaneously being delivered to Gary J. Buehler, Director, Office of Generic Drugs, and Daniel M. Troy, Chief Counsel, and to representatives of Bristol-Myers Squibb Co. ("Bristol") and American BioScience, Inc. ("ABI").

<sup>1</sup> Now called IVAX Research, Inc. This petition will use the name "BNP," because that is the name used in other documents related to the issues addressed in, and submitted with, the petition.

<sup>2</sup> All further section numbers are to Title 21 unless otherwise specified.

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**A. Action Requested.**

BNP requests the Commissioner of Food and Drugs (“Commissioner”) to commence a proceeding to determine that BNP’s abbreviated new drug application (“ANDA”) for paclitaxel, ANDA 75-184, is not required to contain a certification to Patent 6,096,331 (“the ‘331 patent”) as a condition of final, effective approval because the ‘331 patent was not timely listed.

If FDA determines that the ‘331 patent was timely listed, BNP requests that as part of the proceeding FDA determine that:

- No 30-month stay of effective approval under § 355(j)(5)(B)(iii) will be imposed on the BNP ANDA if BNP submits a certification under § 355(j)(2)(A)(vii)(IV) (“¶ IV certification”) to the ‘331 patent; or
- Because the approval of ANDA 75-184 was mistakenly and unlawfully delayed, the effective approval date should be corrected, nunc pro tunc, to a date that precedes August 11, 2000.

BNP requests that the Commissioner expedite review and disposition of this petition.

BNP specifically requests that the Commissioner do the following:

1. Establish a public docket for the proceeding requested by this petition.
2. Within five days of the date of receipt of this petition, publish a Notice in the Federal Register (a) stating that this petition has been received, and that a docket has been established for purposes of determining whether the ‘331 patent was timely listed and ruling on the other issues stated above, and (b) inviting comments on, and information relevant to, the issues raised in the petition.
3. Specify in the Notice that such comments must be received within 10 business days of the date of publication of the Notice in the Federal

Register, and that BNP must submit any reply comments within 5 additional business days.

4. Make a determination on the issues raised in this petition within 10 business days of the date by which BNP must submit reply comments.
5. State in the Federal Register Notice that, in the exercise of its enforcement discretion, FDA will take no action to require BNP to terminate marketing of paclitaxel meeting the conditions set out in ANDA 75-184 pending the determination specified in ¶ 4.
6. Immediately notify BNP, through the undersigned, whether it agrees to the procedures and schedule above.

**B. Statement of Grounds.**

**1. An Expedited Proceeding Is Both Practical and Necessary.**

On November 6, 2001, the U.S. Court of Appeals for the District of Columbia Circuit issued a decision in American BioScience, Inc. v. Thompson, 269 F.3d 1077 (D.C. Cir. 2001). The court of appeals directed the district court to vacate the order of the Food and Drug Administration ("FDA") approving ANDA 75-184, and remand the matter to the Agency. ANDA 75-184 authorizes BNP to market paclitaxel, an important anticancer drug. On January 10, 2002, BNP's petition for rehearing and for rehearing en banc was denied. The mandate of the court of appeals will issue on January 17, 2002.

The court of appeals held that FDA's decision to approve BNP's ANDA was unsupported by the administrative record. The ANDA did not contain a certification to the '331 patent. The Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act") requires a patent to be listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") within 30 days of issuance. §§ 355(c)(2) and 355(e)(4). Under FDA's regulations, the applicant for a pending ANDA is not required to submit a certification to a patent listed after the time limit. 21 C.F.R.

§ 314.94(a)(12)(vi). FDA determined that the '331 patent was listed after the 30-day time limit, and therefore that BNP's ANDA could be approved without a certification to the '331 patent.

The court of appeals held that, on the then existing administrative record, it was arbitrary and capricious for FDA to conclude that the '331 patent listing was untimely. However, that administrative record did not contain most of the documents that are relevant and material to the issue of the timeliness of the listing of the '331 patent. Those documents were not in the record because there was insufficient opportunity to submit them before FDA ruled on the matter.

The initial issue for FDA on remand, therefore, will be (1) whether, on a full administrative record, the '331 patent was timely listed. BNP also asks FDA to determine (2) that, if the patent was timely listed, no further 30-month stay may be imposed on the approval of BNP's ANDA if BNP amends the ANDA to include a ¶ IV certification to the '331 patent or (3) that, due to Agency error, the review and approval of the ANDA were mistakenly and unlawfully delayed, and that the date of the approval should therefore be corrected to a date that precedes the date of the '331 patent listing.

These are discrete and narrow issues. As a result of the litigation leading to the court's November 6 decision, the factual issue of the timeliness of the '331 patent listing has already been the subject of intensive and comprehensive exploration by BNP, FDA, ABI, the holder of the '331 patent, and Bristol, which submitted the '331 patent to its new drug application ("NDA") for Taxol. The parties are knowledgeable not only about the information in the administrative record considered by the court, but also about information outside that record that is relevant to whether the '331 patent was timely listed. That additional information is submitted with this citizen petition. The issue of the timeliness of the '331 patent listing can, therefore, be adequately addressed and resolved in a short period of time.

The issue of an additional 30-month stay if the '331 patent is found to have been timely listed raises a legal question, which can readily be briefed and answered within the time proposed. Similarly, the issue of correcting the date of approval of ANDA 75-184 can be resolved expeditiously based on consideration of the legal basis for such action and on information accessible to the Agency as to the reasons for the delay in the original approval.

Because the mandate of the court of appeals will issue in the near future, FDA should initiate and carry out the proceeding requested in this petition on an expedited basis. An order vacating FDA's approval of ANDA 75-184 will potentially disrupt the continued availability of BNP's paclitaxel product. That product currently has approximately 40 percent of the paclitaxel market. See Attachment ("Att.") B-6, Declaration of Neil Flanzraich ("Flanzraich Decl."), ¶ 5. Any interruption in the marketing of BNP's paclitaxel product would have severe consequences for BNP, as well as for cancer patients who need paclitaxel treatment. See id. ¶¶ 7-10.

If FDA adheres to the schedule requested in section A above, the Agency will make a determination as to whether ANDA 75-184 can be immediately reapproved soon after issuance of the district court order vacating the ANDA's currently effective approval. For the reasons explained above, that schedule can easily be met.

As a result of the information submitted with this citizen petition, and based on any comments and information submitted by ABI, Bristol, and any other affected persons, FDA should conclude that ANDA 75-184 is entitled to continued effective approval under the FDCA. Accordingly, FDA should conduct an expeditious proceeding to avoid the possibility of an unnecessary and unjustified interruption in the availability of BNP's paclitaxel product.

## 2. FDA's Review and Approval of ANDA 75-184.

ANDA 75-184 was accepted for filing in October 1977. JA432.<sup>3</sup> The ANDA contained ¶ IV certifications to several patents Bristol had listed in the Orange Book. Notice of the certifications was sent to Bristol. Within 45 days Bristol instituted a patent infringement action, which triggered a 30-month stay of ANDA approval, expiring on June 2, 2000. JA432-33. (For the most part Bristol's patents were held invalid.<sup>4</sup>)

Although there was no legal obstacle to FDA's issuing final effective approval of the ANDA on June 2, the Agency did not do so. Based on several informal communications between BNP and FDA representatives, FDA assumed that the 30-month stay expired in early August 2000. Att. B-6, Declaration of Jane Hsiao, Ph.D. ("Hsiao Decl."), ¶¶ 6-8. Although some technical issues may have remained after June 2, it is likely that substantive review of the ANDA could have been completed in time for final action earlier than August if FDA had realized that the 30-month stay expired on June 2. Id. ¶ 9.<sup>5</sup>

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<sup>3</sup> "JA" refers to the Joint Appendix submitted to the court of appeals in ABI v. Thompson, and submitted with this citizen petition as Attachment A. All citations to the Joint Appendix will specify the "JA" page number without reference to Attachment A. The Joint Appendix contains a significant part of the information relied on by BNP in this citizen petition as to the timeliness of the '331 patent listing. Also submitted with this petition are court documents not included in the Joint Appendix. Those documents are collected in Attachment B. The contents of the Joint Appendix and the court documents are well known to BNP, FDA, ABI – all parties to the litigation – and to Bristol, which was an intervenor in the district court and a party to or participant in most of the events to which the information relates.

<sup>4</sup> Bristol-Myers Squibb Co. v. Ben Venue Labs., 246 F.3d 1368, 1370 (Fed. Cir. 2001).

<sup>5</sup> During the first half of 2000, BNP and FDA also discussed and resolved an issue about the scope of 180-day generic drug exclusivity. Id. ¶ 5. BNP believes that this process would have been completed by June 2, if the agency's internal technical review had been scheduled with the June 2 date in mind.

On August 1, 2000, the '331 patent was issued to ABI. On August 11, in a lawsuit by ABI against Bristol,<sup>6</sup> the United States District Court for the Central District of California entered a temporary restraining order ("TRO") requiring Bristol to list the '331 patent in the Orange Book, which Bristol did on that date.<sup>7</sup> BNP submitted a ¶ IV certification to the '331 patent on August 14. At that time, BNP did not send notice of the certification to Bristol and ABI, because BNP was attempting to intervene in the California litigation to cause the prompt delisting of the '331 patent.<sup>8</sup>

On August 28, 2000, FDA issued a tentative approval of ANDA 75-184. JA71. FDA said final approval would not be issued until the legal and regulatory issues relating to the '331 patent listing were resolved. JA72.

BNP's attempt to intervene in the ABI v. Bristol proceeding in California resulted in pleadings and oral arguments relevant to this citizen petition and described further below. On September 7, the district court dismissed the case, and ordered Bristol to delist the '331 patent. JA90-92. On September 11, Bristol made a second submission to FDA to list the '331 patent. JA93. On September 14, Bristol, in a letter to FDA, withdrew the '331 patent listing "to the extent that listing was compelled by the TRO" but stated that the action did "not affect the continued and continuous listing of the

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<sup>6</sup> American BioScience, Inc. v. Bristol-Myers Squibb Co., No. 00-08577 (WMB) (C.D. Cal.) (filed August. 11, 2000) ("ABI v. Bristol").

<sup>7</sup> The claims of the '331 patent on which the involuntary Orange Book listing was based have been declared invalid. American BioScience, Inc. v. Baker Norton Pharmaceuticals, Inc., No. 00-09589 (MRP) (C.D. Cal.) (filed Jan. 10, 2002).

<sup>8</sup> In the district court in ABI v. Thompson, FDA acknowledged that notice was not considered necessary "due to the unusual nature of the August 11 listing." A notice would have allowed ABI to sue and obtain a stay of approval of BNP's ANDA. The agency explained that "because FDA issued only a 'tentative' approval of [BNP's ANDA] on August 28 until the issues regarding the '331 patent were resolved, Bristol-Myers and ABI got the benefits of a stay without initiating litigation." Federal Defendant's Memo. in Opp. to Plaintiff's Motion for a TRO, pp. 23-24 (JA923-24).

patent, including by the Revised Listing [the September 11 submission] . . . and which remains applicable to all pending and subsequently filed” ANDAs. JA96.

The very next day, September 15, 2000, FDA approved BNP’s ANDA, JA103-05, without an opportunity for BNP to respond to Bristol’s September 14 letter.

**3. The ABI v. Thompson Litigation.**

The district court’s first decision upholding the September 15 approval, ABI v. Shalala, 142 F. Supp. 2d 1 (D.D.C. 2000), was reversed and remanded by the court of appeals based on the absence in the approval letter or elsewhere in the record before the court of FDA’s explanation for why it decided that the ‘331 patent listing was untimely. ABI v. Thompson, 243 F.3d 579 (D.C. Cir. 2001).

On April 6, 2001, FDA submitted a Declaration from Gary J. Buehler, Director of the Office of Generic Drugs (“Buehler Declaration”), setting forth that explanation and attaching the information he considered in making his decision. JA58, 61-68, 69-210. ABI’s motion for a TRO and preliminary injunction were denied by the district court. 141 F. Supp. 2d 88 (D.D.C. 2001).<sup>9</sup> On the second appeal, the court of appeals held that FDA’s approval of ANDA 75-184, as explained in the Buehler Declaration, was still unsupported by the administrative record and was arbitrary and capricious. 269 F.3d 1077. The court directed the district court “to vacate the FDA’s order and remand to the agency.” Id. at 1086. BNP’s petition for rehearing has now been denied.

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<sup>9</sup> The later district court decision is in the earlier volume of West’s Federal Supplement series.

**4. FDA Must Redetermine the Approvability of ANDA 75-184 Based on a Full Administrative Record.**

**a. The Court of Appeals Did Not Foreclose Such a Redetermination.**

The court of appeals decided that Bristol's September 14 letter "clearly indicates that Bristol-Myer's original filing of August 11 had a bifurcated purpose – to comply with the court order and to voluntarily list the '331 patent and accordingly it was abrogating the first but not the second." 269 F.3d at 1085. For this conclusion, the court relied wholly on the Buehler Declaration – which did not address the language in Bristol's September 14 letter that, in the court's view, revealed a "bifurcated purpose" – and on documents attached to that Declaration.

The documents supporting the Buehler Declaration included the TRO entered by the California district court in ABI v. Bristol, Bristol's three patent listing submissions (August 11, September 11, and September 14, 2000), and the California district court's September 7 delisting order. However, the Buehler Declaration did not include, and did not address the significance of, other contemporaneous documents – in existence but not submitted to FDA prior to the September 15 approval decision – that established as a matter of fact that Bristol's August 11 filing of the '331 patent did not have a bifurcated purpose but was, as shown by Bristol's own public statements and actions, wholly involuntary.

Nothing in the November 6 opinion of the court of appeals says or implies that such documents may not be placed in the record of the Agency's review of ANDA 75-184. Further, nothing in the opinion says or implies that FDA is foreclosed from examining those documents, together with documents previously placed in the record, and reaching a different conclusion about the voluntariness of the August 11 listing from the one reached by the court based on the limited selection of documents available to it. The documents available to the court consisted in important part of statements Bristol crafted for purposes of rationalizing Bristol's and ABI's attempted tactical use of the

August 11 listing of the '331 patent to block approval of BNP's ANDA and ANDAs of other applicants for approval of generic paclitaxel. The court did not consider, because it was not in the administrative record, the significant documentary evidence that refutes Bristol's statements in the September 14 letter insofar as they suggested that the August 11 listing was made voluntarily, *i.e.*, for any reason other than the TRO.

Any possible concern that FDA might be foreclosed by the court's decision from redetermining the issue of the voluntariness of Bristol's August 11 listing is dispelled by settled judicial precedent:

If the record before the agency does not support the agency action . . . the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation. The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.

Fla. Power & Light Co. v. Lorion, 470 U.S. 729, 744 (1985). See also County of Los Angeles v. Shalala, 192 F.3d 1005 (D.C. Cir. 1999), *cert. denied*, 530 U.S. 1204 (2000); Williams v. Wash. Metro. Area Transit Comm'n, 415 F.2d 922, 939-40 (D.C. Cir. 1968) (upon remand from court reversing administrative action, agency is "legally free to pursue a valid course of action"). "[T]here is no principle of administrative law that restricts an agency from reopening proceedings to take new evidence after the grounds upon which it relied are determined by a reviewing court to be invalid." PPG Indus., Inc. v. United States, 52 F.3d 363, 366 (D.C. Cir. 1995). FDA is therefore free to reopen the record and receive additional evidence on the voluntariness of Bristol's August 11 listing. See Wilder v. Apfel, 153 F.3d 799, 803 (7th Cir. 1998) (after reviewing court finds evidence insufficient to support agency action, agency on remand may take same action based on new evidence).

Evidence heretofore outside the record convincingly demonstrates that Bristol's August 11 filing was not voluntary, and that statements made by Bristol in the September 14 letter that imply otherwise are contrary to the facts. Because FDA approved BNP's

ANDA the day after Bristol submitted its September 14 letter, BNP had no reason or opportunity to submit this evidence in response to Bristol's September 14 letter for consideration by the Agency in reaching its decision.

**b. It Would Be an Abuse of Discretion for FDA Not to Redetermine the Approvability of ANDA 75-184.**

Not only is FDA free to reopen the proceeding on ANDA 75-184, it would be error for FDA to refuse to do so. When the matter is remanded to FDA, BNP's ANDA will again have tentative approval. Under § 355(j)(5)(A), FDA will be under a statutory obligation to approve or disapprove the ANDA. The only question will be whether the ANDA may be approved without being amended to include a certification to the '331 patent. The answer previously given by FDA to that question has been held invalid by the court of appeals. BNP remains entitled to a valid answer by FDA to that question.

A valid answer depends on a correct determination on a full record as to whether Bristol's August 11, 2000, submission had a "bifurcated purpose," to both satisfy the TRO and voluntarily list the '331 patent. If the August 11 listing was not partly voluntary, then the '331 patent was completely delisted by Bristol's September 14 letter. In that case, any subsequent listing of the '331 patent occurred after the expiration of the 30-day time limit. Under 21 C.F.R. § 314.94(a)(12)(vi), BNP would not be required to make a certification to the '331 patent.

FDA cannot properly refuse or fail to evaluate relevant factual evidence about the voluntariness question when it decides, on remand, whether ANDA 75-184 meets the statutory standards for approval under § 355(j). The September 15, 2000, approval of the ANDA was based on FDA's finding that Bristol's September 14 letter carried out the California court's September 7 order to delist the '331 patent. At that time, FDA did not raise with BNP the possibility that Bristol and ABI would later argue that there was a "voluntary component" to the August 11 listing, and that this voluntary component was not being withdrawn by Bristol. Nor did BNP independently interpret Bristol's letter as

raising that possibility. Even if it had, there was no opportunity for BNP to address that issue before the ANDA approval issued on September 15. After the ANDA was approved, the administrative record was closed and BNP had no reason, or any obvious procedural vehicle, for addressing the issue since FDA's decision was in its favor.

In these circumstances, it would be an abuse of discretion for FDA to refuse to receive and consider information from BNP that is directly relevant to the voluntariness issue. Cf. Eastern Carolinas Broadcasting Co. v. FCC, 762 F.2d 95, 103-04 (D.C. Cir. 1985), in which the court held that an agency's refusal to reopen the record to receive "convincing evidence" was not an abuse of discretion and not reversible error only because the agency provided an alternate basis for its action.

Here BNP is submitting, with this citizen petition, convincing factual evidence that refutes Bristol's self-serving statements in the September 14 letter. Those statements were given credence by the court of appeals due to the absence from the Buehler Declaration and accompanying documentation of the very information BNP proffers in this petition. BNP is entitled to have Mr. Buehler or someone else at FDA reopen the record to reconsider Bristol's September 14 letter in light of this "new evidence [that would] persuade to a contrary result." Cooley v. FERC, 843 F.2d 1464, 1473 (D.C. Cir. 1988) (quoting Friends of the River, 720 F.2d 93, 98 n.6 (D.C. Cir. 1983)).

A finding that the August 11 listing was not voluntary would be dispositive as to the approvability of ANDA 75-184. There is no alternate basis for deciding that the ANDA is not approvable. Accordingly, it would be an abuse of discretion for FDA not to receive relevant and material evidence bearing on the voluntariness issue.

**c. It Would Be Arbitrary and Capricious for FDA Not to Redetermine the Approvability of ANDA 75-184.**

Refusal to receive and consider BNP's evidence would also be arbitrary and capricious. It would potentially result in adverse action – refusal to grant final approval to ANDA 75-184 – without notice to BNP of the proposed basis for that action and

without giving BNP an opportunity to respond to the facts and reasons on which FDA proposes to rely.

An agency may not validly take action against an individual without a hearing unless its notice to the individual of the adverse action proposed to be taken against him specifies the nature of the facts and evidence on which the agency proposes to take action. Such notice enables the affected party to prepare an informed response which places all the relevant data before the agency.

Hess & Clark, Div. of Rhodia, Inc. v. FDA, 495 F.2d 975, 983 (D.C. Cir. 1974) (footnote omitted). See also Williston Basin Interstate Pipeline Co. v. FERC, 165 F.3d 54, 63 (D.C. Cir. 1999) (“It is well-established that ‘[a] party is entitled . . . to know the issues on which decision will turn and to be apprised of the factual material on which the agency relies for decision so that he may rebut it.’” (quoting Bowman Transp. Inc. v. Arkansas-Best Freight System, Inc., 419 U.S. 281, 288 n.4 (1974))).

At no time has FDA given BNP notice that the Agency may refuse to approve ANDA 75-184 on the basis that, because the August 11 listing was partly voluntary and therefore not completely withdrawn pursuant to the September 7 order in ABI v. Bristol, the ANDA is incomplete without a certification to the ‘331 patent. Nor has FDA given BNP an opportunity to submit factual information demonstrating that the listing was not partly voluntary, but, rather, was entirely the result of the August 11 TRO. The proceeding requested by this citizen petition will be the first chance BNP will have to respond on the administrative record to ABI’s and Bristol’s assertions to the contrary.<sup>10</sup>

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<sup>10</sup> In the ABI v. Thompson litigation, BNP identified significant evidence showing that the August 11 listing was not voluntary. However, because that evidence had never been placed in the administrative record, and had not been relied on by FDA in its decision to approve BNP’s ANDA, the court disregarded both the evidence and BNP’s conclusions regarding its significance to the voluntariness issue. ABI v. Thompson, 269 F.3d at 1085-86.

It would therefore be arbitrary and capricious for FDA to refuse to conduct the proceeding requested in this petition.

Statements by the court of appeals in ABI v. Thompson that, in its view, the August 11 listing of the '331 patent was partly voluntary and that the "September 11 letter was simply an effort to add a belt to suspenders," 269 F.3d at 1085 n.10, do not relieve FDA of the obligation on remand to determine independently, on the basis of adequate notice to BNP and a complete record, the voluntariness of the August 11 listing. The court of appeals did not have the benefit of an analysis of the voluntariness issued by FDA based on consideration of all the facts. Moreover, the court could not, and did not purport to, decide ultimate factual issues relating to the August 11 listing. See Fla. Power & Light Co., 470 U.S. at 744 (reviewing court not empowered to reach its own conclusions). It merely held that the record before it and the explanation in the Buehler Declaration were insufficient to justify the September 15, 2000, decision to approve BNP's ANDA.

Indeed, the court might well have taken a different view of the August 11 listing and upheld the approval of the ANDA if FDA had been able to provide a complete and balanced administrative record on the voluntariness issue. Thus it would be perverse if FDA were to conclude that statements of the court attributable to the fact that the administrative record was incomplete and biased now prevent the Agency from granting this petition, whose purpose is to eliminate those very flaws. Such a conclusion would be fundamentally unfair: "[T]he Due Process Clause forbids an agency to use evidence in a way that forecloses an opportunity to offer a contrary presentation." Bowman Transp. Inc., 419 U.S. at 288 n.4 (citation omitted).

**5. The Facts Demonstrate that the August 11 Patent Listing Was Made Solely in Response to the TRO, and Therefore Was Not Partly Voluntary.**

Resolution of the issue whether the '331 patent listing submitted by Bristol on August 11, 2000, was withdrawn by Bristol's September 14 letter depends on the reason

why the August 11 submission was made, and on the words of the September 7 court order. Briefly, Bristol made the August 11 listing because the California court's August 11 TRO required Bristol "to list" the '331 patent. JA76. Entry of the TRO was conditioned on ("subject to") the requirement that Bristol "cause the de-listing" of the '331 patent if no preliminary injunction were entered. Id. Bristol's August 11 letter said that Bristol listed the '331 patent "[p]ursuant to" the TRO. JA78. The September 7 court order required Bristol "to cause the delisting" of the '331 patent. JA91. The September 14 letter said it was "submitted to comply fully with the Court's Order of September 7." JA96.

FDA interpreted this sequence of actions as having the effect of delisting the '331 patent. That interpretation was consistent with the Agency's patent listing regulations at 21 C.F.R. § 314.53. Under those regulations, a patent is either listed or it is not listed. The underlying reason for the decision to list the patent is irrelevant.

Nevertheless, in its analysis of the administrative record, the court of appeals attached significance to statements by Bristol in the September 14 letter characterizing the FDCA and 21 C.F.R. § 314.53 as providing for "voluntary patent listing," that the August 11 listing complied with FDA requirements "for voluntary listings," and that the listing was being withdrawn only to the extent that it was compelled by the TRO. To the court, this meant that there was a "voluntary" component of the August 11 listing that was not withdrawn by the September 14 letter. The court concluded that the purpose of Bristol's original filing of August 11 was in part "to comply with the court order" and in part "to voluntarily list the '331 patent." ABI, 269 F.2d at 1085.

BNP does not, in this petition, ask FDA to depart from the reasoning of the court of appeals that a patent listing can be in part voluntary and in part involuntary. Instead, we demonstrate that the objective facts relating to Bristol's decision to list the '331 patent on August 11 are incompatible with any conclusion other than that the sole purpose of the August 11 listing was to comply with the TRO. Conversely, there are no

contemporaneous facts that are consistent with any purpose by Bristol to list the '331 patent voluntarily.

This demonstration is based both on evidence that was part of the original administrative record relied on in the Buehler Declaration, and on information that was not in that record. The discussion below presents all the relevant information in chronological order. The information in the original administrative record is described at the appropriate point in the chronology, in context with information that was not provided to FDA before ANDA 75-184 was approved. We emphasize, however, that BNP is not asking FDA to base its conclusion that Bristol's August 11 listing was not voluntary on a reevaluation of the record reviewed by the court of appeals. Rather, BNP is asking FDA to reach a new conclusion based on a new and complete record. That complete record, of course, includes the material that was in the original record.

The California lawsuit is obviously central to the issue of the voluntariness of Bristol's August 11 listing. Of the five exhibits attached to the Buehler Declaration that bear on the voluntariness issue (Tabs 2-3 and 5-7), two are orders of the California court, two are letters from Bristol pursuant to those orders, and the fifth is a letter written (according to Bristol) as a result of the second order.

Despite the importance of the California lawsuit to the voluntariness issue, virtually all of the relevant evidence from the California case was not in the original administrative record, and was therefore not relied on by FDA or evaluated by the court of appeals in ABI v. Thompson. This evidence includes, among many other documents, the pleadings in the California case in which Bristol opposes the listing of the '331 patent, declarations of Bristol and ABI that reveal that Bristol was not willing to list voluntarily, and transcripts of court proceedings in which Bristol's lawyer stated that Bristol did not, and would not, list the '331 patent without being ordered to do so by the California court.

It is this much more extensive account of Bristol's refusal to list the '331 patent voluntarily that makes up most of the presentation below. In fact, other than the five exhibits attached to the Buehler Declaration, all of the detailed evidence described next is completely new to the record relating to the voluntariness issue.

**a. The TRO and Bristol's August 11 Listing.**

The ABI v. Bristol lawsuit was prompted by a letter from ABI to Bristol dated August 5, 2000, asking Bristol to list the '331 patent, JA308, and a letter to ABI from Bristol dated August 10, "declin[ing] to list the patent." JA317. ABI alleged in its moving papers on August 11 that Bristol's "decision to decline to list ABI's patent will cause ABI irreparable harm." JA299. On August 11, on the basis of that allegation, the California court ruled that ABI would suffer harm if a TRO were not issued, entered a TRO directing Bristol to list the patent with FDA, required payment of a \$10,000 bond, and set a briefing schedule on ABI's motion for preliminary injunction, including a date for Bristol's opposition and ABI's reply. JA353-54. The TRO included a proviso that the patent would be delisted if ABI did not prevail on its motion for a preliminary injunction, and stated that ABI "must cooperate in any delisting ordered by the Court." Bristol later commented favorably on these two conditions of the TRO, JA340, suggesting that they were included or added at Bristol's request. Compare JA76-77 with JA353-54.

On the same day the TRO was entered, Bristol submitted a patent listing to FDA. JA78-80. Bristol's August 11 letter said:

Pursuant to an order of the United States District Court for the Central District of California, Bristol-Myers Squibb Company, the holder of NDA 20-262 (including all approved supplements) covering TAXOL® (paclitaxel), in accordance with the provisions of 21 C.F.R. § 314.53, submits the attached patent information and declaration for listing in the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

JA78. ABI also submitted a letter to FDA. JA74. It said:

ABI's patent covers the product Taxol® now manufactured and sold by Bristol Myers Squibb Company ("BMY"). Earlier today, Judge William J. Rea, a United States District Judge for the Central District of California, ordered BMY to list ABI's patent in the FDA's Orange Book. A copy of that order is attached hereto.

I wanted to bring this matter to your urgent attention so that you would act appropriately under the circumstances now that the patent has been issued and ordered listed.

Id. There is no contemporaneous evidence from August 11 that at any time on that day Bristol was willing to list the patent voluntarily.

The above actions and statements are evidence that Bristol's August 11 listing was submitted solely to comply with the TRO, and that there was no "voluntary" component to Bristol's action. The most important evidence, perhaps so obvious that it is easy to overlook, is the very existence of the ABI v. Bristol court case, and the TRO issued by the court at ABI's urgent insistence. Neither would have been necessary if Bristol had been willing to submit the '331 patent voluntarily on August 11.

Whether an action is voluntary is a factual matter having to do with whether the person who takes the action does so "without external persuasion or compulsion." American Heritage Dictionary (2d Ed.) (Att. B-7). The facts here are that ABI's lawyer asked Bristol to list the '331 patent on August 5. JA308. On August 10, Bristol's lawyer "declined" to do so. Id. On August 10, ABI's lawyer notified Bristol's lawyer that ABI intended to sue for a TRO, and Bristol's lawyer said Bristol would "consider" the requested relief. Id. The next day, ABI sued, the TRO was entered, and Bristol listed the patent.

This is not a sequence of events in which any voluntariness on Bristol's part can be identified. Bristol was given multiple opportunities to make a decision to list the '331 patent voluntarily. ABI provided Bristol with information about the '331 patent

beginning even before the patent was issued, JA317; and Bristol was in a position to make an informed judgment as to whether there was an adequate basis for listing the patent. Nevertheless, on August 10, Bristol's lawyer stated unequivocally that "Bristol must respectfully decline to list the patent." JA317. Given this statement on August 10, there is no plausible explanation for Bristol's August 11 listing other than that Bristol submitted it under the "external compulsion" of the TRO, i.e., involuntarily.

The TRO, itself, evidences Bristol's unwillingness to list the '331 patent other than on the basis of the "external compulsion" of the TRO. The TRO contained both a proviso that required Bristol to delist the patent if ABI failed to obtain a preliminary injunction, and a condition that ABI cooperate in any delisting. JA353-54. Inclusion of these provisions is evidence that Bristol's listing of the '331 patent was to be governed by, and governed only by, the TRO. If there had been any element of voluntariness in Bristol's decision to list the patent on August 11, the TRO would not have so meticulously provided for the mandatory withdrawal of that listing upon termination of the TRO without a preliminary injunction. Mandatory delisting would have been squarely contrary to a voluntary listing.

The plain language of Bristol's August 11 letter is consistent with an action taken by Bristol only under compulsion of the TRO and not voluntarily. The letter stated that the listing was being made because of the TRO. The letter did not refer to any other reason or purpose for the listing. The letter specifically stated in the same sentence that the patent information was being submitted "[p]ursuant to" the California TRO and "in accordance with" 21 C.F.R. § 314.53. JA78. Bristol's language thus drew a distinction: Bristol was making the submission solely under compulsion of a court order, and was doing so in the manner prescribed by § 314.53. Had Bristol intended its August 11 submission to be partly under compulsion and partly voluntary, the most natural way to have expressed such an intention would have been to say that the submission was being made pursuant to the court order and independently of the court order.

Bristol's compliance with § 314.53 did not show that Bristol was acting "partly" voluntarily. That possibility is contradicted by the district court's August 11 order. The TRO "ordered" Bristol "to cause the FDA to list in its 'Orange Book' ABI's Taxol Patent." JA76. The order also "restrained and enjoined [Bristol] from failing to comply with its statutory and regulatory obligations under 21 U.S.C. § 355(c)(2) and 21 CFR § 314.53(b) and (d)." Id. Thus, the reference in Bristol's August 11 letter to § 314.53 merely documented Bristol's compliance with the TRO. Even if (as Bristol later stated in the September 14 letter (JA95)), FDA's patent listing regulation is "for voluntary patent listing," as a factual matter, Bristol complied with the regulation only because the TRO compelled it to do so by "ordering" the listing and by "restraining and enjoining" Bristol from failing to comply with the regulation. The fact that an action is capable of being taken voluntarily does not mean that a person who refuses to take it when asked to do so and who is then ordered by the TRO to take it has taken the action "voluntarily."

That Bristol's August 11 listing was entirely the result of the TRO is confirmed by Bristol's public announcement of the listing action it took. On August 15, Bristol issued a press release announcing that it "has complied with a temporary restraining order . . . in a suit brought against the company on August 11, 2000, by American BioScience, Inc. As directed by the court, Bristol-Myers Squibb listed an ABI patent [the '331 patent]." Att. B-4, Wendell Declaration, Ex. B. The press release made no reference to any "voluntary component" of the August 11 listing.

ABI, too, understood that Bristol was not acting voluntarily in sending the August 11 letter. ABI's understanding is apparent from ABI's decision to send its own letter to FDA, JA74, telling the Agency that the court had "ordered" Bristol to list the '331 patent. Had Bristol decided, as a result of the TRO, that it would list the '331 patent "partly voluntarily," there would have been no reason for ABI to play policeman to assure Bristol's compliance with the court order.

It may be contended that, although Bristol was unwilling to list the patent voluntarily before the issuance of the TRO (and thus ABI needed the TRO), once the TRO was issued Bristol changed its mind and decided to list voluntarily as well as under the compulsion of that order. However, there is no contemporaneous evidence whatsoever that Bristol underwent such a change of mind. The logical way to have documented such a change of mind would have been by a clear statement to that effect in Bristol's August 11 submission to FDA, followed by a clear statement to the California court; but, as noted, Bristol made no such statement in the August 11 submission or to the court, or in any other forum anywhere else. Moreover, as discussed infra, Bristol's statements and conduct after August 11 are inconsistent with there having been any voluntary aspect to the listing on August 11.

**b. Proceedings in ABI v. Bristol.**

In ABI's California lawsuit, Bristol opposed ABI's motion for a preliminary injunction to maintain the August 11 listing. In its opposition, filed August 16, 2000, Bristol argued that it "should not be put in the position of submitting a patent for listing and then perhaps being required to defend an infringement suit against the very same patent at a later time." JA338. Bristol asserted that it should not be "prejudiced by being the vehicle for the FDA submission to list." JA339. Bristol also argued that, if ABI failed to meet its burden to show that the '331 patent satisfied the statutory listing requirements, then ABI's motion to maintain the August 11 listing "should be denied." Id. To state the obvious, the fact that on August 16 Bristol opposed having to make the listing contradicts the notion that Bristol made the August 11 listing to any extent voluntarily.

On August 17, 2000, ABI replied to Bristol's opposition to the motion for preliminary injunction to compel Bristol to maintain the '331 listing after expiration of the TRO. Att. B-1. This pleading is evidence that the August 11 listing was not voluntary, because ABI believed that it had to continue its effort in court to overcome

Bristol's refusal to maintain the listing. ABI was in a good position to know whether Bristol was – on August 11 or thereafter – willing to list the '331 patent on its own initiative rather than solely under court order. ABI plainly believed on August 17 that Bristol had not listed, and was not willing to list, or to maintain the listing of, the '331 patent voluntarily. Had Bristol been willing to maintain the listing voluntarily, it easily could have so stated and thereby rendered the then pending motion for preliminary injunction moot. But Bristol did not do so.

On August 21, the California court heard arguments on ABI's motion and Bristol's opposition. The court had before it a proposed settlement for which ABI and Bristol were seeking formal court approval. The proposed settlement included, inter alia, a court order that Bristol list ABI's patent. JA446-47. The following is a colloquy between the court and Bristol's lawyer:

The Court: Let me make it clear, I'm prepared to proceed for the one motion that's before me, and that's the motion, the motion on the preliminary injunction. That one, while it's been briefed by you, I guess you in effect are withdrawing your opposition to it if I approve the settlement.

Mr. Solomon: That's correct, Your Honor. Only if the court approves the settlement. If not, then we ought to proceed --

JA464-65. As of August 21, then, Bristol was still unprepared to list the '331 patent voluntarily. Only if the court approved a settlement between ABI and Bristol that ordered Bristol to list the patent would Bristol list it. If it did not, then Bristol was willing "to proceed" to the motion then before the court, which was ABI's motion for a preliminary injunction to require Bristol to maintain the listing. Bristol opposed that motion. The court did not approve the proposed settlement between Bristol and ABI on August 21, or thereafter. Only the TRO, therefore, accounts for Bristol's continued listing of the '331 patent as of August 21.

During the August 21 hearing, the lawyer for ABI also made statements that constitute factual evidence of Bristol's unwillingness to list the '331 patent on August 11. ABI's lawyer stated that, prior to August 11:

We had strenuous negotiations and demands that they list. We supplied them with what we believed to be the necessary statutory declarations. There is particular declarations that are required under the FDA statute. Rather than requiring Bristol to have someone sign that our patent covered their product, we had the flexibility of our two patent lawyers and inventor providing those declarations. Bristol declined to list after, much to our chagrin, last Thursday [August 10]. We immediately gave ex parte notice that we would be in here on Friday for a TRO.

JA443-44. Later, ABI's lawyer and the court had the following exchange with respect to the proposed settlement:

Mr. Coyne: We want a court order, Your Honor, because --

The Court: But you want a court order where the court makes the specific finding as to something or other --

Mr. Coyne: Well, as --

The Court: -- to be a little vague about it, and it's the something or other that the intervenors [i.e., BNP] aren't too crazy about.

Mr. Coyne: No, I don't think they complain about the factual finding. They may, but we require -- we require after this month of trying to get Bristol-Myers to do what they could have unilaterally done, we believe, Your Honor, they could have filed and listed this patent without this court proceeding. So that's the thing. They declined to do it.

We've asked in our settlement for two things: one, a finding that we've met the reasonably-can-be-asserted standard in the act, and then, two, that they are ordered to find it, because -- to list the patent.

JA446-47. On August 21, therefore, ABI's lawyer represented to the court that ABI "required" an "order" to Bristol to list the '331 patent because after a "month" of trying to persuade Bristol to list the patent "unilaterally," i.e., voluntarily, Bristol still "declined to do it."

On August 23, ABI filed an amended complaint. Att. B-2. Count 20 states that Bristol "declined to list the ['331] Taxol Patent in the FDA's Orange Book." Id. at 8. ABI would have known, as a factual matter, whether or not Bristol had refused to list the '331 patent. Counts 21 and 22 refer to the TRO ABI had to obtain to overcome Bristol's refusal to list the patent voluntarily and to Bristol's post-TRO "attempt to avoid its statutory obligation to continue to list the Taxol patent." Id. As of August 23, therefore, ABI believed Bristol had not listed the '331 patent voluntarily and that Bristol was continuing to refuse to list the patent. Certainly, ABI would have known whether or not this was the case; and ABI's submission of an amended complaint and the continuation of the ABI v. Bristol lawsuit are strong evidence that ABI's assertion was accurate: Bristol did, and was continuing to, refuse to list the '331 patent voluntarily, and Bristol never advised the California court otherwise.

On August 29, ABI filed an opposition to BNP's motion to intervene in the California litigation. Att. B-3. As of that date, ABI stated that "this case is about forcing BMY [Bristol] to comply with its statutory duties" to list the '331 patent, Att. B-3, p. 4 (emphasis added), and that "[i]n this case, ABI only seeks to compel BMY to comply with its statutory obligations." Att. B-3, p. 7 (emphasis added). ABI stated that ABI and Bristol had reached a settlement – never carried out – under which Bristol would again be ordered to list the '331 patent, but under terms acceptable to Bristol. Att. B-3, p. 10. None of these assertions is consistent with any other state of facts than that Bristol had listed the '331 patent on August 11 not voluntarily, but solely under compulsion of the TRO, and that as of August 29 Bristol would not voluntarily continue to list the patent unless the court ordered it to do so.

On August 29, ABI also filed a reply to BNP's opposition to ABI's motion for preliminary injunction. JA534. In response to BNP's argument that Bristol should be ordered to delist the patent, ABI argued:

[I]f BNP's request to delist the ABI patent is granted, ABI will suffer enormous irreparable harm due to the requirement that a patent must be listed in the Orange Book within 30 days. . . . Here, the ABI patent was issued by the PTO on August 1, 2000 and thus the 30 day period expires on August 31. If the patent is delisted, then it could not be listed again within the 30 day period and ANDA applicants would not be required to file paragraph IV certifications.

JA559-60 (citations omitted). Therefore, ABI argued, the court should issue a preliminary injunction. ABI knew at that time whether Bristol had listed the '331 patent partly voluntarily, and obviously knew that Bristol had not done so. For its part, BNP was asking the California court to carry out the terms of the TRO, not to order Bristol to withdraw a "voluntary" listing of the '331 patent. JA422. If there had been such a voluntary listing on August 11, one that would survive delisting of the TRO-required listing, then ABI's quoted statements would have been inaccurate. There is no reason why they would not have been accurate, however. The passage quoted from ABI's reply also shows that it was understood that a delisting ordered by the court would not leave in place any timely listing; and that, in that circumstance, ABI would "suffer enormous irreparable harm."

On August 29, Bristol, too, filed an opposition to BNP's motion to intervene. Att. B-4. On page 6 of the pleading, Bristol stated:

The TRO required that Bristol "shall *immediately* take all steps under its control to cause the FDA to list in its 'Orange Book' ABI's TAXOL Patent" (Solomon Decl., Ex. C (TRO, dated August 11, 2000 (emphasis added))). As directed, Bristol immediately submitted the patent information required under the FDCA and applicable regulations to the FDA, using the ABI-supplied declaration to support the submission. The FDA required submission package is neither lengthy nor complex: a

two-paragraph cover letter, a one-page form with basic information concerning the patent (owner, number, type, etc.), and a copy of a one paragraph declaration certifying the listability of the patent (Scullion Decl., Ex. A).

In its desperation to portray Bristol as the wrongdoer (for having complied with a TRO!), Ivax [BNP's parent] would have this Court believe that the format of the listing package submitted to the FDA evidences some conspiracy among or sham by ABI and Bristol. Ivax grossly misleads the Court as to the applicable regulations. For example, the "Time Sensitive Patent Information" stamp on the cover letter to the FDA was not, as Ivax implies, an extraordinary attempt by Bristol to assist ABI (*see* Ivax Mem. of P's and A's re: Intervention, pp. 7-8). The legend is *required* by FDA's own regulations. 21 C.F.R. § 314.53(d)(6). Likewise, Ivax's aspersions as to the sufficiency of the declaration in support of listing the '331 patent (Ivax Mem. of P's and A's re: Preliminary Injunction, p. 5) *ignore* the applicable regulation, 21 C.F.R. § 314.53(c)(2), which dictates the exact language and format of the declaration to be submitted in support of listing. Ivax is well aware of the regulatory requirements for listing a patent.

Att. B-4, p. 6 (underlined emphasis added).

Bristol's argument in the quoted paragraphs is that BNP's allegations of collusion between Bristol and ABI could not possibly be correct because the August 11 listing was not voluntary, *i.e.*, it was done "[a]s directed" by the TRO. If the listing had been "partly" voluntary, Bristol's denial of collusion on the basis stated would have been factually untenable.

Additional material Bristol presented to the California court on August 29 further confirms that Bristol's only purpose in listing the '331 patent on August 11 was to comply with the TRO. Paragraph 2 of an August 29 Declaration from Bristol's employee Bruce J. Wendell filed with Bristol's opposition (Att. B-4) states that on August 15 he advised BNP (specifically, representatives of BNP's parent, IVAX Corp.) that "a TRO had issued that Friday requiring Bristol to submit the patent information to the FDA; and that Bristol had complied with the TRO by submitting the required information to FDA

and listing the '331 patent on Friday afternoon, August 11." Att. B-4, Wendell Declaration, p. 2. Mr. Wendell made no reference to any "voluntary component" of the August 11 submission.

On August 29, Bristol's outside counsel, Louis M. Solomon, in a Declaration submitted with Bristol's opposition (Att. B-4), stated that on August 18, 2000 – after the August 11 patent filing – ABI and Bristol had "reached an acceptable compromise," as a result of which Bristol had become willing to list the '331 patent if the court approved the compromise. Plainly, prior to August 18, Bristol was unwilling to list the patent on any terms without a court order. The proposed compromise – never implemented – was needed because the only reason the August 11 listing was made was that the TRO required it. Had a voluntary listing been made on August 11, a decision by Bristol on August 18 to list the patent if a settlement approved by the court with an order to list would have been unnecessary.

On September 1, Bristol submitted a response to BNP's objections to the ABI-Bristol settlement initially proposed to the court on August 21 and mentioned in the Solomon Declaration. Att. B-5. On page 5 of the pleading, Bristol stated unequivocally that it "is not consenting to a settlement in the absence of a court determination that ABI has in fact carried its burden of demonstrating listability." Att. B-5, p. 5. Because, as of September 1, Bristol still was not willing to consent to listing the '331 patent voluntarily without a court order, it cannot be that on August 11 Bristol had listed the '331 patent voluntarily.

On September 6, the California court held another hearing, to consider further ABI's motion for a preliminary injunction and to consider BNP's motion to intervene. The court asked ABI's lawyer what would happen if the court refused to grant ABI's motion for a preliminary injunction. ABI's lawyer said:

Mr. Coyne: Then if we don't prevail, then Bristol can do what they want to do -- well, the problem is, we can't return to the status quo.

If we had had this hearing before August 30th, Bristol could have then made a unilateral decision. Okay, did they -- did A.B.I. meet its burden; and are we obligated to list? And then they could have listed absent a court order.

The problem is, under Hatch-Waxman, they have 30 days in which to do that so their time to do that has run. So we would be incredibly prejudiced if that were to occur because then it would be unclear whether Bristol-Myers could make a unilateral determination that we had met our burden and that they were required to list under the statute.

JA577. On September 6, that is, ABI believed that Bristol "could have listed absent a court order" but had not done so. Id.

At that hearing, Bristol's lawyer confirmed that at no time prior to September 6 did Bristol have any purpose in listing the '331 patent other than to comply with the TRO:

The Court: You're saying, "Judge, approve this consent decree" is what you're saying to me; right?

Mr. Solomon: That is our request.

The Court: And you want me to approve though it orders you to do something?

Mr. Solomon: Yes, because A.B.I. --

The Court: That you won't do otherwise?

Mr. Solomon: Because A.B.I. wouldn't agree to the deal to present to the court unless it got what it wanted.

\* \* \*

Mr. Solomon: Before this lawsuit started, Bristol found itself caught between a rock and a hard place. It was approached by someone who simultaneously said, "we want you to list our patent, and we hold open the right to sue you." It doesn't matter --

\* \* \*

Mr. Solomon: And we could not find ourselves in that position, and I don't believe, as clear as the statute is, that A.B.I. has the right to have its patent listed. The statute doesn't say who has to carry that burden. We asserted that A.B.I. had to carry that burden. They asserted that we had to carry that burden. This was not just semantics. This is very important because in the certification --

The Court: Then why don't we litigate it?

Mr. Solomon: If the court will not enter that order, then we are prepared to litigate. . . .

JA604-06. In other words, even as of September 6, Bristol was still not prepared to list the '331 patent voluntarily, *i.e.*, without a court order, in part because Bristol understood that it did not have a basis for representing to FDA that the '331 patent met the statutory listing criteria. That being the case, it is clear that, as a factual matter, Bristol could not have listed the '331 patent voluntarily on August 11, because Bristol did not then believe it was legally appropriate to do so. Bristol's lawyer went on to say on September 6: "It is Bristol, however, that does not want and I don't believe under the statute has to be put in the position of vouching one way or the other for the validity of this patent." JA609.

Bristol's unwillingness to be seen as "vouching for" the '331 patent is significant as to whether the August 11 listing was voluntary. Although Bristol's listing contained declarations only from ABI under 21 C.F.R. § 314.53(c)(2) (as is permitted by (c)(4)), had Bristol submitted the listing voluntarily it would have attached it to a FDA Form 356h (Att. B-8) (*see* 356h, p. 2, checklist item 13), which only Bristol could have signed. The form would have required Bristol to state that "[t]he data and information in this submission have been reviewed and, to the best of my [*i.e.*, Bristol's] knowledge are certified to be true and accurate." Had Bristol signed this statement, it would have "vouched" that the '331 patent met the statutory standard in § 355(c)(2) for patent information, specifically, that the '331 patent "claims" Taxol and also that ABI could reasonably assert a claim against Bristol for infringing the '331 patent by selling Taxol.

Only by filing the '331 patent listing under compulsion of the TRO, and not voluntarily, could Bristol have been able to maintain that it was not "vouching for" the '331 patent, as Bristol's counsel insisted Bristol refused to do. Therefore, the August 11 listing was not done voluntarily, and on September 6 Bristol remained unwilling to list the '331 patent voluntarily.

**c. The September 7 California Court Order.**

After the hearing on September 6, the California court dismissed ABI's lawsuit. JA90-92. The court stayed its order until September 13 to give ABI a chance to seek a stay pending appeal. The order stated in part:

4. The Temporary Restraining Order ("TRO") issued by Judge William J. Rea on August 11, 2000, requiring BMY [Bristol] to take all steps under its control to cause the listing of plaintiff's '331 Patent in the FDA publication known as "Approved Drug Products with Therapeutic Equivalence Evaluations" or the "Orange Book," is dissolved. Pursuant to the condition in the TRO and in order to restore the status quo, BMY shall use its best efforts to cause the delisting of plaintiff's '331 Patent from the Orange Book. ABI shall cooperate with BMY in its efforts to delist the '331 Patent pursuant to the TRO;
5. Prior to the entry of the TRO, BMY had twenty days remaining under the Hatch-Waxman Amendments, 21 U.S.C. § 355(c)(2), to cause the listing of plaintiff's '331 Patent in the Orange Book. This Court recommends to the FDA that the time that the TRO was in effect should toll the period in which BMY may timely cause such listing.

JA91-92.

The court included the recommendation to FDA to toll the 30-day period based on the facts presented by Bristol and ABI in the form of the statements they made about the August 11 listing. Those statements were that the August 11 listing was made only because the TRO compelled it due to Bristol's having "declined" to make the listing voluntarily, and that Bristol continued to refuse to list the '331 patent voluntarily. The

court was told by the parties to the proceeding, in other words, that as a result of the absence of a voluntary listing by August 31, compliance with the court's September 7 order would entirely withdraw the '331 listing. The court's recommendation to toll the 30-day period was included in the order solely because of these facts. If Bristol had voluntarily listed ABI's patent on August 11, in addition to listing it pursuant to the TRO, there would have been no reason for the California court to recommend that FDA toll the 30-day period for submission of patent information so that Bristol could voluntarily submit such information in a timely manner if it so chose.

Nor is there any evidence in the text of the September 7 order that the August 11 listing was made by Bristol partly voluntarily. Aside from the fact that both Bristol and ABI had represented to the court the previous day that they wanted the court to proceed with the case specifically because the listing was and remained involuntary, the September 7 order gave effect to the conditions in the TRO that were included by the court on August 11 on the understanding that Bristol would list the '331 patent only under the compulsion of the TRO, i.e., the conditions that, if the TRO expired without a preliminary injunction, Bristol was to delist the patent and ABI was to cooperate in the delisting. The effectuation of those conditions in the September 7 order is further evidence that the factual assumption on which the conditions were based was accurate. That assumption was that the August 11 listing was made only to comply with the TRO, i.e., it was wholly involuntary.

**d. Bristol's September 11 Listing.**

On September 11, 2000, Bristol filed a lawsuit in the Southern District of New York for declaratory relief as to its obligation to submit information on the '331 patent. JA730. Had Bristol already listed voluntarily, of course, there would have been no basis or purpose for this lawsuit.

In the Complaint, Bristol described the August 11 filing as one prompted by the TRO, JA731, 740, and further alleged:

Unless the Court of Appeals stays the district court's order dissolving the TRO, BMS [Bristol] intends to comply with the order by seeking withdrawal of the listing that BMS submitted pursuant to the TRO. However, based upon materials submitted by ABI in support of its lawsuit . . . BMS today [i.e., September 11, 2001] submitted for listing in the Orange Book information about the ABI patent. This will preserve the status quo while this suit proceeds.

JA732 (emphasis added). As a matter of plain English, these statements mean that the September 11 listing was a different patent listing from the August 11 listing. If Bristol thus intended to say that the September 11 listing was a continuation or revision of the August 11 listing, it would have used words that conveyed that meaning. That Bristol used words describing the September 11 listing as different from the August 11 listing is evidence that the August 11 listing was involuntary, because, if it was partly voluntary and would therefore remain in effect, there was no logical reason for Bristol to submit a new, independent, listing. Moreover, Bristol explained its September 11 listing as one made to "preserve the status quo," i.e., not necessarily a permanent listing.

Bristol's September 11 listing letter stated:

Pursuant to 21 U.S.C. § 355(b)(1) and implementing regulations, BMS hereby submits for listing in the agency's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") the enclosed information about U.S. Patent No. 6,096,331. The submission includes the required declaration by the patent owner.

JA93. This letter contains no evidence that the August 11 listing was voluntary. On the contrary, it is persuasive evidence that the August 11 listing was involuntary, i.e., made solely to comply with the TRO. First, if the August 11 listing had been partly voluntary, the September 11 letter would have been unnecessary, because the August 11 listing would have remained in effect despite the court's delisting order. Second, if the purpose of the September 11 listing was to confirm or revise the August 11 listing, Bristol would have stated that purpose in the September 11 letter, which it did not do. In fact, the

September 11 letter does not even mention the August 11 letter. Third, the contrast in language between the August 11 submission and the September 11 submission is striking: the former was submitted “pursuant to the [TRO]”; the latter was submitted “[p]ursuant to [the FDCA].” The former was under compulsion of the TRO; the latter was not. Fourth, the most logical inference to be drawn from the September 11 letter is that, because Bristol was aware that the California court’s September 7 delisting order was due to take effect on September 13, and would require Bristol to entirely withdraw the August 11 listing, a new listing had to be submitted independent of the TRO for the ‘331 patent to remain in the Orange Book.

ABI acknowledged the significance of the September 11 listing in a Declaration dated September 15 submitted by its counsel in the district court in the District of Columbia in ABI v. Thompson:

Attached as Exhibit E is a copy of the Order entered by the Court on September 7, 2000. While it does order [Bristol] to delist the patent listed pursuant to the TRO, Paragraph 5 of such order expressly provides that [Bristol] may list the patent voluntarily, and in fact recommends that the FDA toll the period the TRO was in effect – approximately 20 days – to allow [Bristol] to do so. Pursuant to this order, [Bristol] listed the patent voluntarily on September 11, 2000.

JA751 (Declaration of Joseph F. Coyne, Jr.) (emphasis added). This statement constitutes evidence that the August 11 listing was not voluntary, because it implicitly contrasts that listing with the listing that ABI said was voluntary – the September 11 listing. ABI thus told the District of Columbia court that Bristol had made a voluntary listing on September 11 (not on August 11).

**e. Bristol’s September 14 Withdrawal Letter.**

On September 13, the stay of the court’s September 7 order expired. On September 14, Bristol sent a letter to FDA. JA95-96. The letter stated that, although the August 11 listing was “made in accordance with” the TRO, it was “also timely filed in

full compliance with all governing statutory and regulatory requirements for voluntary patent listing.” JA95. This statement is not evidence that Bristol listed the ‘331 patent voluntarily on August 11.

First, it does not say – and Bristol has never said anywhere – that, on August 11, Bristol listed the ‘331 patent voluntarily. From all the evidence described at pp. 17-33, supra, Bristol was compelled to submit the ‘331 listing on August 11 by the external compulsion of the TRO. The September 14 letter does not say that, contrary to that evidence, Bristol, in fact, made the listing “partly” voluntarily. Such a statement (if it had been true) was so plainly called for by the other statements in the letter, so simple to make, and so obviously in Bristol’s interest that its absence from the September 14 letter can be explained only by Bristol’s unwillingness to make it and inability to truthfully make it. The absence from the September 14 letter of a simple, declaratory statement by Bristol that it made the August 11 listing voluntarily or partly voluntarily is, in the context of Bristol’s other statements about “regulatory requirements for voluntary patent listing,” evidence that the August 11 listing was not voluntary.

Second, use of the word “also” in characterizing Bristol’s compliance with the listing provisions is deceptive. It implies that Bristol’s “full compliance” with the patent listing requirements of the statute and regulations, as distinct from the submission of the listing, was not compelled by the TRO. On the contrary, the TRO expressly “restrained and enjoined” Bristol from failing to comply with those very requirements. JA76. Therefore, Bristol’s “full compliance” with those requirements is not evidence of voluntariness, but of obedience to the compulsion of the TRO.

Third, the September 14 letter further stated:

BMS also submitted a listing on September 11, 2000 (the “Revised Listing”) . . . . The Revised Listing was made pursuant to 21 U.S.C. 355(b)(1) and (c)(2), and was identical to the Original Listing except that it was based, not only on Mr. Reiter’s declaration, but also on two additional declarations prepared by the patent owner. The Revised

Listing was also made in the belief that, as a result of the California litigation, the patent owner has satisfied its burden to show that the patent meets the criteria for listing, and in recognition of, among other things, an Order of the District Court. . . .

JA95. The September 11 submission, itself, did not call the September 11 listing a "Revised Listing." Bristol's September 11 letter simply stated that Bristol was submitting the '331 patent information. It did not state that its purpose was to "revise" the August 11 listing. It did not mention the August 11 listing. The very absence of any reference to the August 11 listing in the September 11 submission is evidence that the September 11 listing was independent of the August 11 listing. That, in turn, is evidence that the August 11 listing was involuntary, because, if it was voluntary, there was no need for an independent, voluntary listing on September 11.

The quoted paragraph contains further evidence that the August 11 listing was involuntary. It says that the September 11 listing was made in the belief that ABI had shown, "as a result of the California litigation," that the '331 patent met the listing criteria. That showing did not occur until after August 11, because there was no "litigation" until then, and ABI and Bristol did not reach their settlement agreement until August 18.

The quoted paragraph also states that the September 11 listing was "in recognition of" the California court's order. Bristol thus referred to the second bullet on JA96, which states and then paraphrases the September 7 order's tolling recommendation as permitting Bristol "to submit a new patent listing, which should be considered to have been timely listed" (emphasis added). According to Bristol's own words, therefore, the September 11 listing was a "new patent listing." The "new patent listing" was necessary because the August 11 listing was made solely to comply with the TRO, *i.e.*, involuntarily. The only purpose of the court's recommendation was to have FDA toll the 30-day period to permit a "new" voluntary patent listing to be made, because the August 11 listing was not voluntary.

Fourth, after summarizing the main provisions of the September 7 California court order, Bristol's September 14 letter states:

This letter is submitted to comply fully with the Court's Order of September 7, 2000. Thus:

- BMS hereby withdraws the Original Listing to the extent that listing was compelled by the TRO; and
- This action does not affect the continued and continuous listing of the patent, including by the Revised Listing, which continues in effect pursuant to 21 U.S.C. 355(b)(1) and (c)(2) and paragraph 5 of the Court's Order, and which remains applicable to all pending and subsequently filed abbreviated new drug applications.

JA96. Bristol's statement that the letter is "to comply fully" with the September 7 order is evidence consistent with the involuntary nature of the August 11 listing. The September 7 order states "[p]ursuant to the condition in the TRO and in order to restore the status quo, BMY [Bristol] shall use its best effort to cause the delisting of plaintiff's [ABI's] '331 patent from the Orange Book." JA91.

Nowhere in that language, or elsewhere in the September 7 order, is there any mention of a "voluntary component" of the August 11 listing that was outside the scope of the TRO and that would remain unaffected by "full compliance" with the September 7 order. Indeed, preservation of the August 11 listing would have been contrary to the stated purpose of the September 7 order to "restore the status quo." Rather, the court assumed that the August 11 listing was entirely the result of the TRO's compulsion, had no separate "voluntary" component, and would, therefore, in accordance with the TRO and the September 7 order, be withdrawn in toto. Because the court believed the August 11 listing was entirely involuntary, and based its order on that factual assumption, Bristol's statement that it was fully complying with the court's order is factual evidence that the August 11 listing was entirely involuntary, and that the September 14 letter necessarily withdrew the August 11 listing in its entirety.

The first bullet in the material quoted above is not evidence that Bristol submitted the August 11 listing voluntarily. Bristol says it “hereby withdraws the Original Listing to the extent that listing was compelled by the TRO.” As the evidence described above demonstrates, the August 11 listing was made solely to comply with the TRO. Thus, “the extent” to which the August 11 listing was compelled by the TRO was total. There is no evidence that Bristol had any motivation other than the TRO for making it. Bristol does not, in the quoted language, say there was. Therefore, once the August 11 listing was withdrawn, “to the extent that listing was compelled by the TRO,” there was nothing left.

The “continued and continuous listing” language used by Bristol in the September 14 letter is also not evidence that the purpose of the August 11 submission was, in part, to voluntarily list the ‘331 patent. The strongest evidence on that point consists of the factual circumstances of that action at the time it was taken and during the time when ABI was attempting (according to ABI) to “force” Bristol to continue to list the patent (Att. B-3, at 4) and Bristol was (in Bristol’s words) “prepared to litigate” (JA606) to oppose listing the ‘331 patent unless the California court ordered Bristol to list it. As explained, all the facts show that, at the time Bristol submitted the listing on August 11, Bristol did so solely to comply with the TRO, and no facts show that the listing was voluntary.

The “continued and continuous” language is not a factual statement about what Bristol’s purpose was on August 11. The evidence presented at pp. 17-33, supra, shows that Bristol’s only purpose was to comply with the TRO. Nor is it a statement of Bristol’s purpose in the September 14 letter: Bristol had already stated its purpose in that letter, “to comply fully with the Court’s Order of September 7, 2000.” JA96.

Rather, Bristol’s “continued and continuous” language is an obscurely worded post facto suggestion of a legal argument that the August 11 listing should be treated by FDA as continuing in effect, apparently on the ground that it was submitted in the form required by FDA’s listing regulation and somehow (unspecified) survived full

compliance with the September 7 order. The order, of course, recommended that FDA toll the 30-day time limit. Tolling would not have been needed for continuous listing from August 11 on, but only for a new listing after August 31.

The “continued and continuous” language is, in sum, not a description but an argument. It cannot alter the historical fact that on August 11 the only reason Bristol listed the ‘331 patent was that it was compelled to do so by the TRO. Agencies should view self-serving statements by interested parties with skepticism, particularly when those statements are not supported by contemporaneous evidence. See Mohave Elec. Coop., Inc. v. NLRB, 206 F.3d 1183, 1193 (D.C. Cir. 2000); City of Orrville v. FERC, 147 F.3d 979, 991-92 (D.C. Cir. 1998); cf. United States v. Mahoney, 247 F.3d 279, 283 (D.C. Cir. 2001) (district court, acting as fact finder, was entitled to reject defendant’s “post hoc self-serving explanation”).

Bristol’s probable reasons for including the “continued and continuous” language in the September 14 letter further support the conclusion that the phrase is not evidence that the August 11 submission had, as one purpose, to list the ‘331 patent voluntarily. Although the record of the ABI v. Bristol litigation does not contain a clear explanation of Bristol’s strategy, it seems reasonable to assume that Bristol wanted the benefit that the listing of the ‘331 patent would bring – a delay in generic competition with Taxol – but did not want to expose itself to antitrust liability by unilaterally listing a patent that was plainly invalid as applied to Taxol (and which has now been judicially held to be invalid).

The best way to minimize such exposure was to obtain a court order requiring Bristol to list the ‘331 patent. This strategy was viable until September 7, when the court in California dismissed ABI’s lawsuit. But until that time, Bristol’s strategy required that the August 11 listing be involuntary on Bristol’s part, *i.e.*, that it be solely attributable to a court order. Any “purpose” by Bristol to list the ‘331 patent voluntarily, if it could be proved, would potentially be evidence that Bristol had violated § 2 of the Sherman Act in

monopolizing, or attempting to monopolize, the market for paclitaxel in the U.S. Therefore, Bristol clearly did not have such a purpose on August 11, and it never said it did. What Bristol had was an unstated wish that the '331 patent be listed, but not by voluntary act of Bristol.

On September 7, Bristol had to change its strategy. On September 11, it listed the '331 patent assertedly for the sole purpose of preserving the status quo for its lawsuit in New York, filed on the same date. If challenged, Bristol could seek to defend the September 11 listing as Bristol's effort merely to preserve the jurisdiction of the New York court to give full relief.<sup>11</sup>

For Bristol's initial strategy to work, however, the '331 patent listing had to have occurred no later than August 31. The district court, carrying out the terms of the TRO, had defeated Bristol's original strategy by ordering Bristol to withdraw the August 11 listing so as to "restore the status quo." Accordingly, in the September 14 letter, Bristol included carefully worded statements suggesting post hoc that the August 11 listing had some existence apart from the TRO (and was, therefore, not completely "compelled by" the TRO and would not be completely eliminated by compliance with the September 7 order), and that the September 11 listing was a "revision" of that listing (as well as an attempt to submit a new listing within the "tolled" 30-day period).

The "continued and continuous" language of the letter was an attempt to suggest that, notwithstanding Bristol's withdrawal of the August 11 listing Bristol submitted to comply with the TRO, a listing of the '331 patent still remained in some form. This listing "continued" as a result of the September 11 submission, and it was "continuous," because it dated back to August 11 (because the August 11 submission met the requirements of the statute and regulations).

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<sup>11</sup> The lawsuit having served its purpose as a pretext for the listing, Bristol voluntarily dismissed it on October 17. See Att. B-10.

f. **Bristol's District Court Memorandum in  
ABI v. Thompson.**

On September 28, 2000, in ABI v. Thompson, Bristol submitted a memorandum "with respect to" ABI's request for an order against FDA's approval of BNP's ANDA on September 15. JA940-48. In this document, Bristol elaborated on the post hoc argument implicit in the language it used in the September 14 letter. Bristol said it "listed and intended to list" the '331 patent on August 11, and it was the "timing of the listing [that] was initially compelled by the temporary restraining order." JA941.

It may be that Bristol "intended" to list the patent on August 11, but nevertheless Bristol submitted the listing only because it was compelled to do so by the TRO, i.e., involuntarily. A person can "intend" to carry out an action it is being compelled to take. Bristol is thus saying only that it "intended" to comply with the TRO. Bristol's memorandum did not say that, in listing the patent on August 11, Bristol did so both to satisfy the TRO and also to list the patent voluntarily, or that, if there had been no TRO, it would have listed the patent anyway. The memorandum could not have said those things, because in the ABI v. Bristol proceeding Bristol had told the California court that it did not, and would not, list the patent without a court order, and Bristol said that as late as September 6. See pp. 28-29, supra.

Bristol's memorandum also said that Bristol "confirmed the listing based on a toll of the 30-day period recommended by" the California court. JA941. But FDA did not toll the 30-day period, and the September 11 listing, far from "confirming" the August 11 listing, did not even mention it.

Bristol's memorandum further said that Bristol "followed the orders of the California district court and maintained the listing." Id. The California court did not order Bristol to maintain the listing. It ordered Bristol to delist the '331 patent. See p. 30, supra. The memorandum said that on August 18 "Bristol acknowledged the propriety of the listing" but "did not and . . . could not do more to list the Patent at that time." JA943. But Bristol, "at that time" and thereafter, refused to list the patent unless

the California court ordered it to do so on the terms provided in the settlement agreement between ABI and Bristol, which the court refused to do. Therefore, assuming Bristol knew of “more” that it could have done to list the patent on August 18, Bristol would have refused to do it, as shown by Bristol’s own statements and actions in the California court.

Moreover, there was “more” that could have been done. Bristol could have sent a letter to FDA saying it was listing the ‘331 patent not under compulsion of a TRO, but because the ‘331 patent qualified for listing under FDA’s patent listing regulation. In fact, that is exactly what Bristol did – on September 11. It is simply contrary to the facts that Bristol became willing to list on August 18 – within the 30 days – but was unable to find a way to signal its change of position. The facts are that on September 6, Bristol was “prepared to litigate” to prevent the listing; and that, if it had wanted to list the patent voluntarily on August 18, it could easily have done so, but did not.

Bristol’s memorandum states that the California court “directed that Bristol take steps to withdraw the listing of the Patent, but only to the extent the listing was made pursuant to the TRO. The Court nowhere prohibited Bristol from continuing the listing.” JA945-46. The California court’s September 7 order did not say “only to the extent the listing was made pursuant to the TRO,” and therefore it is incorrect to suggest, as Bristol did in the memorandum, that the court implied that there was some aspect of the listing that was not compelled. It is of course correct that the September 7 order, enforcing the condition of the August 11 TRO, reversed only the actions the August 11 TRO compelled. It does not follow that there were other actions that the TRO did not compel, such as a “partly voluntary” listing by Bristol on August 11 or thereafter. The only action that took place on August 11 was an involuntary listing by Bristol, compelled by the TRO, and Bristol continued to oppose listing the ‘331 patent without a court order until September 6. Bristol’s full compliance with the September 7 order therefore completely delisted the ‘331 patent, leaving nothing for Bristol “to continue.”

In sum, Bristol's memorandum is a legal argument expanding on the post hoc statements in the September 14 letter that attempt to imply that the historical events from early August to September 7 can be characterized as a "continuous listing" of the '331 patent. Bristol is free to make such a legal argument, meritless though it is. But that legal argument should not be mistakenly viewed by FDA as stating Bristol's intent on August 11. The facts clearly and overwhelmingly demonstrate that Bristol submitted the listing on August 11 solely to comply with the TRO.

**g. Bristol's Strategy Was to List Only if Compelled.**

What explains Bristol's conduct during August and September 2000? Plainly, it was in Bristol's interest for ABI's patent to be listed because, if multiple 30-month stays are authorized by the FDCA, the listing of ABI's patent would delay market entry by generic paclitaxel products (including BNP's product) and thereby prolong Bristol's paclitaxel monopoly. Yet Bristol repeatedly refused to list the patent voluntarily, provoked a lawsuit by ABI to compel it to list the patent, and when ordered to list it did so with alacrity.

It cannot be said with certainty what Bristol's thinking was. One hypothesis, however, does explain all of Bristol's conduct: that, due to antitrust concerns, Bristol throughout August and at least until September 11, 2000, sought to bring about a listing pursuant to court order but not otherwise.

ABI applied for its patent in 1997, JA138, and received it on August 1, 2000, id. Paclitaxel has been in medical use since at least 1967, JA483; and Bristol's paclitaxel was approved in 1992, Orange Book 3-270 (Att. B-9). Therefore, it is obvious that a claim that ABI's patent covers Bristol's paclitaxel is invalid.<sup>12</sup> Consequently, a voluntary

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<sup>12</sup> Although Bristol presumably is by far the largest infringer of ABI's patent, ABI has never sued Bristol for patent infringement. ABI sued BNP, see supra, p. 7 n.7, and the court has issued summary judgment that the '331 patent claims that cover Bristol's approved paclitaxel product are invalid.

listing by Bristol of such an obviously invalid patent would potentially subject Bristol to treble-damages liability under Section 2 of the Sherman Act for monopolization of the paclitaxel market. Therefore, Bristol was unwilling to list the patent voluntarily. However, a listing compelled by a court order arguably would give Bristol a defense against such a claim. Therefore, Bristol maneuvered to obtain a court order directing it to list the patent. This hypothesis explains the following Bristol conduct:

- Bristol's rejection of ABI's pre-litigation request that it list the patent (i.e., without a court order compelling it to do so).
- Bristol's listing of the patent immediately after issuance of the TRO on August 11, 2000, but with a clear statement that the listing was pursuant to the TRO.
- Bristol's entrance into a settlement agreement with ABI that provided for continued listing of the patent, but only pursuant to court order. Had Bristol been concerned only about a potential lawsuit by ABI (as it advised the California court), that concern could have been put entirely to rest by a covenant not to sue (or agreement by ABI not to use Bristol's listing against Bristol), without any need for a court order. Bristol advised the California court (JA604-06) that, if the settlement (including the provision for a court order) were not accepted, its preference was to litigate ABI's motion for a preliminary injunction.
- In its memorandum in opposition to ABI's motion for a preliminary injunction, Bristol declined to inform the California court that controlling Ninth Circuit precedent precluded ABI's cause of action entirely. Bristol was aware of the relevant case law, as shown by its statement in its opposition to ABI's motion for a preliminary injunction that Bristol "reserves the right to assert that ABI's claim for damages, as opposed to its request for injunctive relief, does not state a claim by reason of the absence

of any private right of action under the statutes sued on.” JA346. The case law, including the controlling Ninth Circuit case, Fiedler v. Clark, 714 F.2d 77, 79 (9th Cir. 1983), also precluded ABI’s claim for injunctive relief, but Bristol did not so inform the California court. The California court ultimately dismissed ABI’s Complaint in reliance on this case law, brought to its attention by BNP in its memorandum in opposition to ABI’s motion for a preliminary injunction. JA406-07.

- Bristol’s filing of the lawsuit in the SDNY on September 11, 2000, in an effort to obtain a court order declaring that it was required to list the patent.
- Bristol’s submission to FDA of the September 11 letter, under cover of the September 11 lawsuit, in which it characterized the letter as preserving the status quo until the court ruled, see p. 32, supra, thereby giving it an arguable defense if the September 11 letter ever became the basis for an antitrust claim against it.
- Bristol’s peculiar language in the September 14 letter, in which it argued for the continued effectiveness of the August 11 listing without ever actually saying that it had been voluntary, and thus without creating a contempt of the California court’s September 7 order.

While stating in its September 14 letter its purpose to comply fully with the September 7 order and so establishing its defense to any charge of contempt, Bristol laid the groundwork for someone else – FDA or a court – to find that the August 11 listing somehow survived the September 7 order for delisting and the September 14 withdrawal in “full[] compl[iance]” with it.

Whether or not FDA accepts this hypothesis, the fact is that Bristol has never characterized its August 11 submission as in any way or to any extent voluntary. The contemporaneous facts surrounding that submission and the subsequent statements and conduct by Bristol and ABI confirm that the August 11 submission was not voluntary.

**h. Conclusion.**

The '331 patent was listed more than 30 days from its date of issuance. ANDA 75-184 was pending at the time the '331 patent was listed. Under 21 C.F.R. § 314.94(a)(12)(vi), BNP has no obligation to certify to the '331 patent. Therefore, the ANDA is complete and must be given effective approval under §§ 355(j)(5)(A) and (B).

**6. The FDCA Does Not Authorize FDA to Withhold Approval of BNP's ANDA Because of a Second, 30-Month Stay.**

Even if Bristol's August 11 listing was found to be timely, FDA may not withhold approval of BNP's ANDA on the ground that an infringement lawsuit after notice of a ¶ IV certification to ABI's '331 patent triggers a 30-month stay. BNP certified to Bristol's patents in 1997, and Bristol sued BNP for patent infringement. The filing of that lawsuit triggered the statutory 30-month stay under § 355(j)(5)(B)(iii), which expired on June 2, 2000. The subsequent filing of patent information cannot trigger a second 30-month stay of effective approval of BNP's ANDA.

The Act provides that a patent infringement action postpones the effectiveness of ANDA approval for up to 30 months, but the plain statutory text states that, upon expiration of the 30-month period, FDA "shall," if the ANDA otherwise meets the statutory standards, approve it under § 355(j)(5)(A) and make the approval effective under § 355(j)(5)(B)(iii). The Act does not authorize patent holders, such as ABI, to obtain additional stays to delay effective approval beyond the initial 30-month period. If there is any ambiguity in the statute that would justify a different interpretation, then the underlying purpose of the Act and its legislative history provide a powerful argument that the Agency should rule that only one 30-month stay is permitted. To permit patent holders to obtain multiple 30-month stays would fundamentally alter the balance that Congress sought to achieve, and would undermine Congress's stated purpose of promoting expedited approval of generic drugs.

**a. The Plain Text of the FDCA Permits Only a Single 30-Month Stay.**

The Hatch-Waxman Amendments to the FDCA provide a mandatory timetable by which the FDA must issue effective approval to ANDAs that contain ¶ IV certifications. Specifically, the statute provides that, if a patent holder files an infringement action within 45 days of receipt of notice of the ¶ IV certification (as Bristol did in 1997), “approval [of the ANDA] shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i),” unless the district court makes a determination on the patent’s validity before expiration of the 30 months. § 355(j)(5)(B)(iii) (emphasis added).

The reference to “the thirty-month period” is to one thirty-month period, the one triggered by the first patent infringement lawsuit filed after notice of a ¶ IV certification. The text does not allow the possibility of multiple 30-month periods. Courts have held repeatedly that the word “‘shall’ to be the language of command” in a statute. Southwestern Bell Corp. v. FCC, 43 F.3d 1515, 1521 (D.C. Cir. 1995) (citation omitted). Congress’s use of the critical word “shall” in § 355(j)(5)(B)(iii) is a clear and unequivocal directive to FDA to make approval of an ANDA effective upon expiration of the 30-month stay. The statute nowhere permits FDA to avoid this mandatory duty, and thereby delay approval beyond the 30-month period, for any reason, including additional ¶ IV certifications to subsequently listed patents. Once FDA tentatively approves an ANDA, its task of making that approval effective is nondiscretionary and purely ministerial.<sup>13</sup>

We understand that FDA has taken the position in recent litigation that the FDCA permits more than one 30-month stay. See Andrx Pharm., Inc. v. Biovail Corp., 2001

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<sup>13</sup> The only exception to this mandatory feature of the Hatch-Waxman Amendments is where the district court hearing the patent infringement action shortens or lengthens the 30-month stay period because “either party to the action failed to reasonably cooperate in expediting the action.” § 355(j)(5)(B)(iii).

U.S. Dist. LEXIS 16904 (S.D. Fla. Sept. 19, 2001). There, Andrx argued that a patent holder may trigger a 30-month stay only on the basis of notice of a ¶ IV certification contained in the ANDA as originally filed, because the stay provision refers only to § 355(j)(2)(B)(i). FDA responded that § 355(j)(2)(B) relates to notices of ¶ IV certifications in both original and amended ANDAs, and that the reference in the stay provision should, therefore, be interpreted as including amended ANDAs.

However, Andrx did not raise, and FDA did not address, the critical word “shall” in the stay provision, itself. As discussed supra, “shall” is a word of command that directs FDA to make approval of an ANDA effective upon expiration of the 30-month period. It is immaterial whether the 30-month stay is triggered by a paragraph IV certification in an original ANDA or in an amended ANDA. Once the 30-month period expires, FDA is required to make the ANDA approval effective. The statute does not require, authorize, or contemplate more than one 30-month stay of the effectiveness of ANDA approval.<sup>14</sup>

**b. If the Statutory Language Is Ambiguous, then the Policy Underlying the FDCA and the Legislative History of the FDCA Provide a Powerful Basis for the Agency to Conclude that Only One 30-Month Stay Should Be Permitted.**

If there is any ambiguity in the statute, it is resolved by the underlying purpose of the stay provision and its legislative history. Congress adopted the stay provision to strike a reasonable balance between the competing interests of NDA sponsors and patent holders and those of generic drug manufacturers. The House Committee on Energy and Commerce observed in its report on the 1984 law that allowing patent holders to sue

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<sup>14</sup> The Court accepted Andrx’s alternative argument that the 30-month stay should be shortened under § 355(j)(5)(B)(iii). Although the Court found that Andrx’s argument that the FDCA permits only one 30-month stay had “some merit,” it concluded that it was unnecessary to resolve this issue. Andrx Pharm., 2001 U.S. Dist. LEXIS 16904, \*33-34.

generic drug manufacturers before the generic drug maker begins marketing “fairly balances the rights of a patent owner to prevent others from making, using, or selling its patented product and the rights of third parties to contest the validity of the patent or to market a product which they believe is not claimed by the patent.” Drug Price Competition and Patent Term Restoration Act of 1984, H.R. Rep. No. 98-857, Part I, at 28 (1984). The House Judiciary Committee, which also considered the legislation, similarly stated that the stay provision

was added by the Committee on Energy and Commerce to accommodate the competing concerns of the [Pharmaceutical Manufacturers Association (PMA)] and the generic manufacturers. The PMA was willing to compromise on the provisions of title I of the bill (relating to abbreviated new drug application procedures (ANDAs)) in exchange for some greater protection of existing human pharmaceutical patents. The generic manufacturers, on the other hand, were willing to live with an eighteen month rule [subsequently extended to 30 months] because of other provisions in the bill.

H.R. Rep. No. 98-857, Part 2, at 9-10.<sup>15</sup>

In reaching this compromise, Congress rejected a proposed amendment that would have delayed effective approval of a generic drug until a patent had expired or a district court had made a final decision that the patent in question was invalid. See id. at 9. That proposed amendment was rejected because “a requirement that FDA defer generic approval until after a court decision of patent invalidity would substantially delay FDA approvals.” Id. at 10. In other words, Congress determined that final resolution of patent rights would not serve as a barrier to generic drug entry to the market. Once 30 months expired, Congress believed, it was more important to provide the public with the benefit of the generic drug than to wait until private parties reached final resolution of a property

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<sup>15</sup> The original bill considered by the House Committee on Energy and Commerce provided a shorter stay of 18 months. Congress later extended the stay provision to 30 months.

rights dispute. As a result, Congress gave FDA no discretion to delay approval of the generic application for more than 30 months. The Committee on Energy and Commerce wrote: once either the expiration of 30 months or the district court's resolution of the patent infringement action "occurs and the approval of the ANDA becomes effective, then the FDA has discharged its statutory responsibility with respect to making the approval of the generic drug effective." H.R. Rept. 98-857, Part 1, at 27. Congress did not intend for more than one 30-month stay – that is, more than one patent dispute – to 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. FDA does not evaluate whether patents submitted for listing in the Orange Book qualify under the FDCA's listing standard and, therefore, does not question whether a 30-month stay is triggered by valid patent dispute or by a patent filed pretextually to obstruct approval of a generic drug. If FDA refuses to screen patent listings and recognizes multiple stays, brand-name drug companies can manipulate the 30-month stay provision by making sequential patent applications and obtaining at different times different patents claiming aspects of the same drug, resulting in a series of 30-month stays that would prevent generic competition for long periods of time. In this case Bristol would enjoy an additional 30 months of marketing exclusivity by virtue of listing a third party's invalid patent to which Bristol, itself, holds no license. Such a result is plainly at odds with the underlying purpose of the Hatch-Waxman Amendments, which was "to expedite the approval of generic versions of namebrand drugs that already have FDA approval, thus making available more low-cost generic drugs." Teva Pharm., USA, Inc. v. FDA, 182 F.3d 1003, 1004 (D.C. Cir. 1999)(citation omitted).

The case of the ABI patent illustrates how permitting additional 30-month stays could create the kind of substantial delay that Congress sought to avoid. BNP's ANDA was filed in October 1997, and Bristol sued for patent infringement. The 30-month

period began to run from the time Bristol received notice, and it expired on June 2, 2000. FDA should have made approval effective as of June 2000, but its failure to do so allowed ABI to file an infringement action in September 2000 that (if, contrary to the argument made in section 5, Bristol submitted notice of the patent within the 30-day deadline) would trigger a second 30-month stay. As a result, the approval of BNP's ANDA would not become effective until March 2003, over five-and-one-half years after BNP made its initial application. Such a delay may affect not only the initial ¶ IV ANDA, but also subsequent ¶ IV ANDAs, because the effectiveness of their approvals can depend on effective approval of, and marketing under, the initial ¶ IV ANDA. See § 355(j)(5)(B)(iv). Congress certainly did not envision such lengthy delays in bringing generic drugs to market.

**7. FDA Should Review the Record and Decide Whether it Would Be Appropriate to Make BNP's ANDA Effective, Nunc Pro Tunc, as of a Date Prior to August 11, 2000.**

BNP's ANDA was accepted for filing on October 7, 1997. Att. B-6, Hsiao Decl., ¶ 3. A paragraph IV lawsuit was instituted on December 1, 1997. Id. Under 21 U.S.C. § 355 (j)(5)(B)(iii), approval of the ANDA would have been effective on June 2, 2000, the date of the expiration of the 30-month stay, if all other issues had been resolved prior to that time. However, for reasons that can be determined only by the Agency, FDA failed to grant tentative approval to BNP's ANDA until August 28, 2000, seventeen days after the listing of the '331 patent on August 11, 2000.

The cost to BNP of the delay in approval is potentially enormous, particularly in light of the rejection by the D.C. Circuit of FDA's finding that Bristol had not "timely" listed ABI's '331 patent. Had FDA tentatively approved BNP's ANDA 18 or more days earlier (i.e., prior to August 11, 2000, when Bristol submitted the '331 patent to FDA for listing), BNP's ANDA approval would remain effective, whether or not the '331 listing was timely. If FDA were to decide that it is appropriate to make the approval effective as

of August 10 or earlier, then it would be unnecessary to resolve whether Bristol's August 11, 2000 listing was withdrawn by its September 14, 2000 letter.

The basis for redating the approval would be the mistake that FDA made in calculating the 30-month period. If, as appears likely, at least 18 days of the delay in approval could have been avoided had FDA been aware that the 30-month stay was due to expire on June 2, 2000, FDA should consider remedying that error by approving the ANDA, nunc pro tunc as of a date prior to August 11, 2000.

In late April or early May 2000, over a period of approximately three days, Jane Hsiao, Vice Chairman of Technical Affairs, BNP, had several conversations with Robert West, Acting Deputy Director, Office of Generic Drugs, in which it became clear that FDA had miscalculated the 30 months. Id. ¶¶ 6-8. Initially, Dr. Hsiao informed Mr. West that the 30 months would expire on June 2, 2000, as a reminder that it was important to resolve all outstanding issues prior to that time. Id. Mr. West responded that Dr. Hsiao was not correct, and that the 30-month stay did not expire until early August 2000. Id. After conferring with one of BNP's attorneys, Dr. Hsiao called Mr. West back to reiterate her prior statement that the expiration date was actually June 2, 2000. Id. Mr. West then checked his information and called Dr. Hsiao back to say that she was correct that the 30-month stay would expire on June 2, 2000. Id.

Only FDA has the information necessary to determine whether the Agency's mistake delayed the August 28 approval of BNP's ANDA by 18 days or more. Based on information known to BNP, however, it appears that at least some of the delay in approving BNP's ANDA was due to FDA's error in calculating the date of the 30-month stay.

There were no major difficulties that had to be surmounted in the approval process, and BNP responded quickly to all requests for information by FDA. The Office of Generic Drugs ("OGD") sent BNP a "major deficiency" letter on November 8, 1999, to which BNP responded on December 8, 1999. Id. ¶ 4. On April 17, 2000, OGD

notified BNP of minor deficiencies, to which BNP responded on April 21, 2000. Id. In late May, OGD asked BNP to submit stability data on the product eighteen months after production. Because the BNP product was only sixteen months old, this testing could not be done until late July. The results were submitted to FDA on July 18, 2000. Id.

During the first half of 2000, BNP and FDA also discussed an issue concerning the scope of the 180-day generic drug exclusivity that would be granted to BNP on approval of its ANDA. Id. ¶ 5. It appears likely that this issue could have been resolved prior to June 2, 2000, had FDA realized that the 30-month stay would expire on that date. In any event, the issue was resolved successfully on July 21, 2000, and would not interfere with a determination that the ANDA could have been approved prior to August 11, 2000.

The foregoing facts suggest that at least 18 days of the delay in ANDA approval could have been avoided had FDA been aware that the 30-month stay was due to expire on June 2, 2000. In light of these facts, BNP submits that the Agency should review the record of the approval process for BNP's ANDA, and consider whether nunc pro tunc approval of the ANDA, as of a date prior to August 11, 2000, is warranted.

FDA has authority to correct its own error by granting nunc pro tunc approval to BNP's ANDA. See American Trucking Ass'n, Inc. v. Frisco Trans. Co., 358 U.S. 133, 145 (1958) (agency had authority to modify certificate of public convenience, where agency inadvertently failed to include condition in original certificate; "the presence of authority in administrative officers and tribunals to correct such errors has long been recognized – probably so well recognized that little discussion has ensued in the reported cases"); Bell v. Hearne, 60 U.S. 252 (1856) (Commissioner of the General Land Office has authority to correct a mistake in the issuance of a patent by canceling the patent and issuing a new one).

Indeed, courts have ordered agencies to remedy an agency mistake by retroactive implementation of the correct order. In McElroy Elec. Corp. v. FCC, 990 F.2d 1351

(D.C. Cir. 1993), for example, the court held that an order of the Federal Communications Commission had misled petitioners as to the filing dates for cellular licenses and therefore the Commission had erred in dismissing applications as untimely. The court concluded that the option to refile the application did not provide a sufficient remedy, because in the interim “the rules of the game [had] changed, generally not to petitioners’ benefit.” Id. at 1358. The court ordered the FCC to reinstate the applications nunc pro tunc, despite its recognition that the reinstatement of the petitioners’ applications “could disturb the rights and expectations of those who benefited from the Commission’s subsequent actions,” including those who had been granted markets and had made investments based on the FCC decisions. Id. at 1365. See also Salzer v. FCC, 778 F.2d 869 (D.C. Cir. 1985) (applicant for low power television license did not receive adequate notice of when and how pending LPTV applications were to be amended to include required supplemental information; case remanded to FCC for reinstatement of application nunc pro tunc); Delta Data Sys. Corp. v Webster, 744 F.2d 197 (D.C. Cir. 1984) (FBI erred in awarding contract without giving disappointed bidder opportunity to explain financial data; proper remedy was to give plaintiff the right to require the FBI to make a nunc pro tunc reselection, after giving plaintiff an opportunity to discuss data).

The facts of this case present at least as compelling a basis for nunc pro tunc approval of BNP’s application as did those in McElroy and the other cases discussed above. The effect of an order vacating approval of ANDA 75-184 would be enormous. Equally compelling is the cost to cancer victims nationwide, who may lose access to a generic version of Taxol that accounts for virtually the entire market of generic Taxol products, one of America’s most widely used anti-cancer drugs. The cost to consumers of BNP’s generic version of Taxol is approximately 40% to 60% lower than the price Bristol had charged before BNP’s product entered the market. Att. B-6, Flanzraich Decl., ¶ 5. Bristol has responded with an almost 40% decrease in the cost of its product. Id. If BNP’s generic paclitaxel is removed from the market, Bristol will have little or no

incentive not to raise its price to the pre-generic level. *Id.* Finally, unlike the situation in *McElroy*, granting nunc pro tunc treatment to BNP's ANDA would not disturb the rights and expectations of anyone who has relied on the expectation that Bristol (by virtue of ABI's patent, to which Bristol has no license) will have exclusive access to the market for an additional period of time. BNP's generic drug is already on the market. ABI has no paclitaxel product on the market and none that could even be approved within the relevant time period. It is thus the removal of BNP's drug from the market that would cause hardship.

**8. FDA Should Allow Marketing of Paclitaxel Meeting the Conditions of ANDA 75-184 Pending a Decision on the Issues Presented in this Citizen Petition.**

If the September 15, 2000, approval of ANDA 75-184 is vacated, FDA should exercise its enforcement discretion to permit BNP to continue marketing paclitaxel that meets the conditions specified in ANDA 75-184. Such marketing should be permitted until FDA acts on this citizen petition. FDA has exercised enforcement discretion in a variety of circumstances involving the lack of regulatory approval. Most recently, the agency permitted the continued marketing of levothyroxine sodium products without NDA approval in accordance with a 1-1/2 year phase-out schedule. Guidance for Industry, Levothyroxine Sodium Products, Enforcement of August 14, 2001, Compliance Date (July 2001). FDA took into consideration the fact that, although there were two approved NDAs, it would take time for patients to be switched to approved products and for manufacturers of approved products to be able to meet the demand.

Different, but equally valid, considerations justify a similar exercise of enforcement discretion with respect to BNP's paclitaxel product. BNP's product currently has about 40 percent of the total paclitaxel market. Att. B-6, Flanzraich Decl., ¶ 5. Abrupt cessation of this source of paclitaxel is likely to cause disruption in the procurement of paclitaxel by health care providers. Moreover, based on its information, BNP believes that other manufacturers with approved ANDAs are not in a position to

provide generic paclitaxel in quantities sufficient to replace BNP's product (even assuming the approved status of those ANDA is unaffected by the November 6 ABI v. Thompson court decision). Therefore, paclitaxel will become essentially a sole source drug available primarily from Bristol, with the resulting potential for a substantial price increase. Att. B-6, Flanzraich Decl., ¶ 7.

BNP's paclitaxel product is a safe and effective drug, fully interchangeable with Bristol's paclitaxel product. Therefore, there is no public health or safety concern from continued marketing of BNP's product. The reason for any withdrawal of final effective approval of BNP's ANDA will relate solely to a factual question as to the timeliness of Bristol's listing of ABI's patent, not to the quantity of BNP's paclitaxel product.

There will be no prejudice to anyone from the interim marketing of BNP's paclitaxel product. Bristol has no rights under ABI's patent. ABI has no paclitaxel product to sell, and it is fully able to enforce the '331 patent while interim marketing occurs. In any event, the '331 patent has been invalidated in ABI's infringement suit against BNP. Finally, this citizen petition requests an expedited resolution of the issues relating to whether BNP's ANDA must contain a certification to ABI's '331 patent. Therefore, the interim marketing we request will not be prolonged. Given that, for the reasons described in this petition, FDA is likely to reapprove BNP's ANDA, interrupting the marketing of BNP's paclitaxel would be unnecessary and unjustified.

**C. Environmental Impact.**

This petition is categorically excluded from the environmental impact statement requirement under 21 C.F.R. § 25.31.

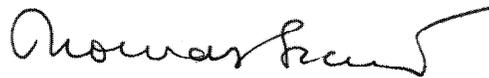
**D. Economic Impact.**

The Commissioner has not requested economic impact information at this time.

**E. Certification.**

The undersigned certifies, that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,



Thomas Scarlett

TS/sas  
Attachments

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