



**Volume IX, Issue 1,  
Fall 2002**

---

**CASE ANALYSIS -  
IN RE BUSPIRONE PATENT AND ANTITRUST  
LITIGATION**

.....Tim Meade  
.....Professor Hildreth  
.....Patent Seminar  
.....St. John's University School of Law  
.....4/18/02

## **Background**

Section 1 of the Sherman Act<sup>1</sup> criminalizes any conspiracy to restrain trade or commerce within the United States or with foreign nations. Section 2 of the Sherman Act<sup>2</sup> criminalizes any attempt to monopolize any part of trade or commerce within the United States or with foreign nations.

In determining the type of conduct that is prohibited by the Sherman Act, the United States Supreme Court articulated what is now known as the Noerr-Pennington doctrine in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*,<sup>3</sup> and *United Mine Workers v. Pennington*.<sup>4</sup> In *Noerr*, the Supreme Court held that “the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint in trade or a monopoly.”<sup>5</sup> In *Pennington*, the Supreme Court held that “[j]oint efforts to influence public officials do not violate the

---

<sup>1</sup> Sherman Act, 15 U.S.C. § 1 (2000).

<sup>2</sup> *Id.* § 2.

<sup>3</sup> 365 U.S. 127 (1961) (holding that attempts to influence the passage or enforcement of laws do not violate the Sherman Act). Noerr filed suit on behalf of truck operators and their trade association against 44 eastern railroads, an association of railroad presidents, and others. Noerr alleged a violation of sections 1 and 2 of the Sherman Act based on the eastern railroads publicity campaign against the Noerr truckers. The campaign attempted to foster the adoption of laws and law enforcement practices destructive of the trucking business and to create an atmosphere of distaste for the truckers among the general public. Noerr alleged this publicity was designed to restrain trade in and monopolize the long-distance freight business since it was aimed at the elimination of truckers in the long-distance freight business.

<sup>4</sup> 381 U.S. 657 (1965) (holding that *Noerr* shielded from the Sherman Act a concerted effort to influence public officials regardless of intent or purpose). Pennington alleged United violated sections 1 and 2 of the Sherman Act by negotiating a minimum wage agreement with the Secretary of Labor for coal miners.

<sup>5</sup> 365 U.S. at 136.

antitrust laws even though intended to eliminate competition. Such conduct is not illegal, either standing alone or as part of a broader scheme itself violative of the Sherman Act.”<sup>6</sup>

The Supreme Court formulated two exceptions for conduct that is not entitled to Noerr-Pennington protection. In *California Motor Transport Co. v. Trucking Unlimited*,<sup>7</sup> the Supreme Court stated “that there may be instances where the alleged conspiracy ‘is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor and the application of the Sherman Act would be justified.’”<sup>8</sup> “Sham” litigation is defined as a two-tier process.<sup>9</sup> In the first step of the process, “the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.”<sup>10</sup> The second step is when the “baseless lawsuit conceals ‘an attempt to interfere *directly* with the business relationships of a competitor’<sup>11</sup> through the ‘use of the governmental *process* -- as opposed to the *outcome* of that process -- as an anticompetitive weapon.’”<sup>12</sup>

---

<sup>6</sup> 381 U.S. at 670.

<sup>7</sup> 404 U.S. 508 (1972) (holding that although California Motor Transport Co. has a right of access to courts, if their purpose was to eliminate Trucking Unlimited as a competitor by denying them free and meaningful access to agencies and courts, a violation of the Sherman Act would exist). Trucking Unlimited applied for certificates as highway carriers. California Motor Transport Co. instituted state and federal proceedings seeking to resist and defeat the applications filed by Trucking Unlimited. Trucking Unlimited alleged that the concerted effort to institute proceedings was in violation of sections 1 and 2 of the Sherman Act as a conspiracy to monopolize trade and commerce in the transportation of goods.

<sup>8</sup> *Id.* at 511 (quoting *Noerr*, 365 U.S. at 144).

<sup>9</sup> *Prof'l Real Estate Investor, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 61 (1993).

<sup>10</sup> *Id.* at 60.

<sup>11</sup> *Id.* at 60-61 (quoting *Noerr*, 365 U.S. at 144) (emphasis added).

<sup>12</sup> *Id.* at 61 (quoting *Columbia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991)).

*Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*

established a second exception to the Noerr-Pennington doctrine.<sup>13</sup> Here, the Supreme Court held that Noerr-Pennington protection would not apply to conduct that a party knowingly and willfully made false representations to the government.

Before an allegation of a conspiracy to monopolize trade or commerce can be analyzed, an objective inquiry into the merits of the conduct that brought about the antitrust allegation must be made. For example, in a lawsuit brought for patent infringement, it must first be determined if the lawsuit for the patent infringement is itself objectively baseless before inquiring into antitrust consequences in violation of the Sherman Act.

### **Current Discussion**

*History: In re Buspirone Patent Litigation*<sup>14</sup>

In August 2001, the Judicial Panel on Multidistrict Litigation consolidated before the United States District Court for the Southern District of New York three patent infringement suits brought by Bristol-Myers Squibb Company (“Bristol-Myers”) against Danbury Pharmacal, Inc., and Watson Pharmaceuticals, Inc. (collectively “Watson”), and Mylan Pharmaceuticals, Inc., Mylan Laboratories, Inc., and Mylan Technologies, Inc. (collectively “Mylan”). The Panel also transferred twenty-two antitrust suits brought by various plaintiffs against Bristol-Myers and twelve tag-along cases. These cases all

---

<sup>13</sup> 382 U.S. 172 (1965) (holding that Noerr-Pennington immunity does not apply to a party who monopolized a market through threats of patent infringement suits based on a fraudulently obtained patent). *See generally*, RONALD B. HILDRETH, PATENT LAW, A PRACTITIONER’S GUIDE (3rd ed. 1998).

<sup>14</sup> *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 340 (S.D.N.Y. 2002).

involved disputes arising from the manufacture, use, sale, or allegedly anticompetitive conduct relating to activity concerning the drug buspirone,<sup>15</sup> which treats anxiety.

In 1980, Bristol-Myers obtained a patent (the “763 Patent”)<sup>16</sup> covering a method for treating anxiety by the use of a non-toxic anxiolytically-effective dose of buspirone. In order to sell new medication, a pioneer drug company must obtain approval of a New Drug Application (“NDA”) from the Food and Drug Administration (“FDA”) and must conduct research establishing that the drug is safe and effective in use.<sup>17</sup> Bristol-Myers obtained approval from the FDA and began selling buspirone tablets under the name Buspar® in 1986.

On November 21, 2000, less than one day before the ‘763 Patent was set to expire, Bristol-Myers obtained a patent (“365 Patent”) claiming one of the metabolites that buspirone naturally produces in the human body.<sup>18</sup> After obtaining the ‘365 Patent,

---

<sup>15</sup> See *id.* at 343 (citing U.S. Patent No. 4,182,763 (issued Jan. 8, 1980)). Buspirone is a drug that helps to treat anxiety and symptoms of anxiety in humans. Buspirone has the chemical formula of 8-[4-[4-(2-pyrimidinyl)-1-piperazinyl]-butyl]-8-azaspiro[4.5]decane-7,9-dione and exerts its effects through human serotonin 1A receptors located in neurons throughout the human brain. Once ingested, buspirone is naturally metabolized to produce a number of metabolites in the human body, one of which is the 6-hydroxy-metabolite.

<sup>16</sup> U.S. Patent No. 4,182,763 (issued Jan. 8, 1980). This patent claims, among other things, “a method for the palliative treatment of neurosis in which anxiety symptoms are prominent which comprises administering a non-toxic anxiolytically effective dose of buspirone or a pharmaceutically acceptable acid addition salt thereof to a neurotic patient....” and “the method of claim 1 wherein buspirone hydrochloride is employed, and dosage is by the oral route.” *Id.* See also 185 F. Supp. 2d at 345.

<sup>17</sup> 21 U.S.C. § 355(b)(1) (2000) (describing the required contents for filing a new drug application).

<sup>18</sup> 185 F. Supp. 2d at 343. U.S. Patent No. 6,150,365 claims, among other things, “a process for ameliorating an undesirable anxiety state in a mammal comprising systematic administration to the mammal of an effective but non-toxic anxiolytic dose of 6-hydroxy-8-[4-[4-[(2-pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione or a pharmaceutically acceptable salt or hydrate thereof.” U.S. Patent No. 6,150,365 (issued Nov. 21, 2000), available at <http://patft.uspto.gov/netahtml/srchnum.htm> (type patent

Bristol-Myers listed it with the FDA in the Orange Book<sup>19</sup> as covering the uses of buspirone in question. By listing with the FDA, an automatic forty-five day time-period began to run in which Bristol-Myers could bring patent infringement suits against generic competitors, who intended to market generic versions of Buspar®, before the competitors could sue for a declaratory judgment action.

Two competitors of Bristol-Meyers, Mylan and Watson, sought to sell generic buspirone tablets for use in accordance with the FDA approved labeling instructions for Buspar®. Both Mylan and Watson had filed Abbreviated New Drug Applications (“ANDAs”) with the FDA, seeking approval of their respective products.<sup>20</sup>

Bristol-Myers asserts in all of the pending patent and antitrust actions in which it is a party that the “manufacture or sale of generic buspirone by a competitor for use in accordance with the FDA-approved labeling instructions for Buspar® violates, or would violate, the new ‘365 Patent.”<sup>21</sup> These lawsuits triggered an automatic stay of the FDA’s approval of Mylan and Watson’s products for up to the earlier of thirty months or until the relative patent disputes were settled.<sup>22</sup> As a result, Mylan and Watson moved for

---

number in the text box and click “search”) (last visited Sept. 14, 2002) (hereinafter “‘365 Patent”).

<sup>19</sup> U.S. FOOD AND DRUG ADMINISTRATION CENTER FOR DRUG EVALUATION AND RESEARCH, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (THE ORANGE BOOK) (22nd ed. 2002), *available at* Electronic Orange Book Home Page, <http://www.fda.gov/cder/ob/> (last modified August 14, 2002).

<sup>20</sup> *See* U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *CDER New and Generic Drug Approvals: 1998-2002*, at <http://www.fda.gov/cder/approval/b.htm> (last modified May 3, 2002) (alphabetical listing providing the application numbers and approval status of all of Mylan’s and Watson’s ANDAs for buspirone).

<sup>21</sup> 185 F. Supp. 2d at 342, 343.

<sup>22</sup> *See* 21 U.S.C. § 355(j)(5)(B)(iii).

summary judgment on the patent infringement claims.<sup>23</sup> Both parties sought a finding that the manufacture, promotion, and sale of generic buspirone tablets in accordance with the current FDA-approved labeling instructions for Buspar® would not infringe the ‘365 Patent; or, in the alternative, that the ‘365 Patent is invalid. Bristol-Myers opposed this motion and moved for a Markman hearing in which to produce evidence of claim construction.<sup>24</sup> On February 14, 2002, Mylan’s and Watson’s motion for summary judgment was granted, with Judge John G. Koeltl holding that the ‘365 Patent does not cover uses of buspirone.<sup>25</sup>

### The ‘365 Patent

Before the ‘763 Patent expired, Bristol-Myers initiated a series of patent applications resulting in the ‘365 Patent. Bristol-Myers’s prosecution of these applications was triggered by their discovery that the 6-hydroxy metabolite of buspirone has anxiolytic potential of its own and may even be the primary active agent in the causal mechanisms leading to the reduction of anxiety in successful uses of buspirone.<sup>26</sup>

On August 5, 1999, Bristol-Myers submitted the first of a series of patent applications based on this new research. The ‘842 Application claimed, among other things, a process for administering a dose of the 6-hydroxy-metabolite or a prodrug

---

<sup>23</sup> In re Buspirone, MDL No. 1410, slip op. at 6-26 (S.D.N.Y. Feb. 14, 2002)(Order No. 18)(Motion for Summary Judgment on Patent Infringement Claims).

<sup>24</sup> Bristol-Myers had also moved to dismiss claims raised by a number of antitrust plaintiffs under the Sherman Act, 15 U.S.C. §§ 1-2, and analogous state law provisions. See 185 F. Supp. 2d at 363. This matter will be discussed in the section entitled *In re Buspirone Antitrust Litigation*.

<sup>25</sup> 185 F. Supp. 2d at 363.

<sup>26</sup> ‘365 Patent, *supra* note 18.

thereof.<sup>27</sup> A prodrug of a metabolite is a precursor drug that is converted into the metabolite during the ordinary processes of metabolization. Since buspirone is a prodrug of the 6-hydroxy-metabolite, the ‘842 Application claimed the use of buspirone.

On August 8, 1999, Bristol-Myers filed a petition to make the ‘842 Application “special,” qualifying it for expedited processing.<sup>28</sup> However, since the Patent Examiner found two distinctly patentable inventions in the ‘842 Application, one related to the 6-hydroxy-metabolite of buspirone and the other related to buspirone itself, he refused to rule on the petition until Bristol-Myers elected one of the two inventions at issue.

Bristol-Myers elected to pursue a patent limited to the uses of the prodrug buspirone.

The Patent Examiner subsequently rejected the amended ‘842 Application under 35 U.S.C. § 102(b)<sup>29</sup> and 35 U.S.C. § 103(a)<sup>30</sup>, explaining that the elected prodrug buspirone is admitted prior art, the FDA-approved labeling instructions for Buspar® are clear evidence of an on sale bar to the claims, and use of buspirone to treat anxiety was obvious in light of the prior art.

---

<sup>27</sup> 185 F. Supp. 2d at 343 (citing U.S. Patent Application No. 09/368,842, which claimed “a process for ameliorating an undesirable anxiety state in a mammal comprising systematic administration to the mammal of an effective but non-toxic anxiolytic dose of [the 6-hydroxy-metabolite] or a pharmaceutically acceptable acid addition salt, prodrug, or hydrate thereof.”).

<sup>28</sup> See MANUAL OF PATENT EXAMINING PROCEDURE, § 708.02 (6th ed. 1997).

<sup>29</sup> “A person shall be entitled to a patent unless . . . the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States. . . .” 35 U.S.C. § 102(b) (2000).

<sup>30</sup> “A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.” *Id.* § 103(a).



Pursuant to the Patent Examiner's indication, Bristol-Myers filed a divisional application<sup>31</sup> ("161 Divisional Application"),<sup>32</sup> claiming the non-elected 6-hydroxy-metabolite of buspirone. Bristol-Myers also filed four more applications, all of which were continuations-in-part ("CIP Applications") of the '161 Divisional Application. Two of the CIPs used the same language as in the '161 Application, claiming the 6-hydroxy-metabolite and neither buspirone nor any prodrug.<sup>33</sup> The remaining two CIPs, on the other hand, claimed the use of the 6-hydroxy-metabolite as well as buspirone.<sup>34</sup> Although the claims of these four patent applications differed, they all used the same specification to describe the invention. Bristol-Myers then proceeded to abandon the '842 Divisional Application, leaving five applications pending.

Bristol-Myers then filed a Preliminary Communication relating to the validity of the '161 Divisional Application. The Preliminary Communication stated that the subject matter of the '161 Divisional Application was not obvious in light of the prior art, namely the use of buspirone as an anxiolytic agent.<sup>35</sup> Bristol-Myers claimed that the prior art teaches away from the use of the 6-hydroxy-metabolite as an anxiolytic agent because one skilled in the art would know that an effective anxiolytic amount of the 6-hydroxy-metabolite would not result in the bloodstream on every occasion.<sup>36</sup> Bristol-Myers also argued that the term "systematic administration" of the 6-hydroxy-metabolite included

---

<sup>31</sup> See *id.* § 121.

<sup>32</sup> Bristol-Myers amended claim 1 of the '842 Application to delete the word "prodrug" to elect the non-elected claimed subject matter.

<sup>33</sup> See 185 F. Supp. 2d at 346 (citing U.S. Patent Application No. 09/588,221). See also *id.* at 350 (citing U.S. Patent Application No. 09/588,222).

<sup>34</sup> *Id.* at 346, 350 (citing U.S. Patent Application Nos. 09/588,223 and 09/588,220).

<sup>35</sup> See *id.* at 348.

<sup>36</sup> *Id.* at 348.

oral administration of buspirone and the deletion of the term “prodrug” did not narrow the scope of the claimed invention.<sup>37</sup>

The Patent Examiner later rejected two of the CIPs (the ‘220 Application and the ‘223 Application) which claimed the 6-hydroxy-metabolite as well as buspirone under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a). The Patent Examiner reasoned that a public use and on sale bar existed due to the fact that an administration of buspirone inherently yields the 6-hydroxy-metabolite.<sup>38</sup> The Patent Examiner also rejected these two Applications on provisional double patenting grounds, since the two Applications overlapped in scope.<sup>39</sup>

The Patent Examiner then rejected the other two CIPs (the ‘221 Application and the ‘222 Application) that claimed the 6-hydroxy-metabolite and neither buspirone nor any prodrug, and the ‘161 Divisional Application all on provisional double patenting grounds.<sup>40</sup> Bristol-Myers then abandoned the ‘161 Divisional Application and the ‘222 CIP Application to remedy the problem of provisional double patenting. The Patent Examiner agreed to make the sole remaining application (the ‘221 CIP Application) special and have it processed on an expedited basis to have it issue before the ‘763 Patent was set to expire.<sup>41</sup> On November 21, 2000, one day before the ‘763 Patent was set to expire, Bristol-Myers obtained the ‘365 Patent claiming the use of the 6-hydroxy-metabolite, but neither buspirone nor any prodrug.<sup>42</sup>

---

<sup>37</sup> *Id.* at 348.

<sup>38</sup> *Id.* at 348-49.

<sup>39</sup> *Id.* at 349.

<sup>40</sup> *Id.* at 349.

<sup>41</sup> *Id.* at 350.

<sup>42</sup> *Id.* at 350. The ‘365 patent claims: “A process for ameliorating an undesirable anxiety state in a mammal comprising systematic administration to the mammal of an effective

Bristol-Myers hand delivered copies of the '365 Patent to the FDA only hours before the '763 Patent was set to expire.<sup>43</sup> The FDA then suspended approval of Mylan and Watson's ANDAs for generic buspirone, leading to Mylan and Watson's current position that patents for metabolites do not cover uses of their prodrugs under established case law.<sup>44</sup>

In late November 2001, Watson filed suit in the United States District Court for the District of Maryland against Bristol-Myers and the FDA seeking preliminary injunctive relief preventing the listing of the '365 Patent and seeking approval of their buspirone ANDA.<sup>45</sup> Mylan filed a similar suit in the United States District Court for the District of Columbia.<sup>46</sup> The United States District Court for the District of Maryland denied Watson's request for a preliminary injunction on the grounds that the FDA's decision was a purely ministerial act that was entitled to deference since it was neither arbitrary nor capricious.<sup>47</sup> In contrast, the United States District Court for the District of Columbia granted Mylan's request for relief since they had established a likelihood of success on the merits that the '365 Patent did not cover the uses of buspirone as Bristol-Myers contended in its Orange Book listing.<sup>48</sup> Nevertheless, Bristol-Myers obtained a

---

but non-toxic anxiolytic dose of 6-hydroxy-8-[4-[4-(2-pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione or a pharmaceutically acceptable acid addition salt or hydrate thereof." '365 Patent, *supra* note 18 at col. 16, lines 27-32.

<sup>43</sup> See 185 F. Supp. 2d at 350. The prosecution history of the '365 Patent was not given to the FDA at this time.

<sup>44</sup> See *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997); 185 F. Supp. 2d at 350.

<sup>45</sup> See 185 F. Supp. 2d at 350; *Watson Pharms. Inc. v. Henney*, 194 F. Supp. 2d 442 (D. Md. 2001).

<sup>46</sup> See *Mylan Pharms. v. Thompson*, 139 F. Supp. 2d 1 (D.D.C. 2001); 185 F. Supp. 2d at 350.

<sup>47</sup> See *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837, 843-44 (1984).

<sup>48</sup> *Mylan*, 139 F. Supp. 2d 1, 29 (Fed. Cir. 2001).

reversal on appeal of this decision on the ground that no private cause of action exists to delist a drug from the Orange Book.<sup>49</sup>

Meanwhile, the Judicial Panel on Multidistrict Litigation had transferred to the United States District Court for the Southern District of New York a number of patent infringement suits brought by Bristol-Myers against Mylan and Watson and a number of related antitrust suits brought by various plaintiffs against Bristol-Myers.<sup>50</sup> Mylan and Watson moved for summary judgment on the ground that their manufacture and sale of generic buspirone does not infringe the ‘365 Patent, or in the alternative, that the ‘365 Patent is invalid.<sup>51</sup>

### *The Conclusion*

United States District Judge John G. Koeltl concluded that the ‘365 Patent does not cover uses of buspirone based on claim construction, the language of the specification, and prosecution history,<sup>52</sup> or in the alternative, based on 35 U.S.C. § 102(b).

### *Claim Construction*

The ‘365 Patent does not specifically claim the systematic administration of buspirone or of any prodrug of the 6-hydroxy-metabolite.<sup>53</sup> The ‘365 Patent only refers to the 6-hydroxy-metabolite itself. Bristol-Myers conceded that the definition of “dose” as used in claim 1 of the ‘365 Patent refers to an amount of the 6-hydroxy-metabolite to

---

<sup>49</sup> Mylan Pharms. v. Thompson, 268 F.3d 1323, 1333 (Fed. Cir. 2001).

<sup>50</sup> See generally, 185 F. Supp. 2d 340.

<sup>51</sup> See *id.* at 343.

<sup>52</sup> See Markman v. Westview Instruments, Inc., 52 F.3d 967 (Fed. Cir. 1995), *aff’d* 517 U.S. 370 (1996).

be taken at one time or in a period of time.<sup>54</sup> Such a construction is limited to an externally measurable amount of the 6-hydroxy-metabolite ingested into body and does not include an externally measurable amount of buspirone.<sup>55</sup>

### *The Language of the Specification*

The language of the specification in the '365 Patent does not say that "systematic administration" of a dose of the 6-hydroxy-metabolite includes either a dose of the 6-hydroxy-metabolite or a dose of buspirone.<sup>56</sup> The term "systematic administration" has a technical understanding to those in the field of the invention meaning "administration of medicine throughout the patient's system, as through introduction into the bloodstream, as opposed to administration only to a local area of the

---

<sup>53</sup> See 185 F. Supp. 2d at 343 (citing '365 Patent, *supra* note 18 at col. 16, lines 27-32).

<sup>54</sup> *Id.* at 352.

<sup>55</sup> See *id.* at 353.

<sup>56</sup> *Id.* (citing '365 Patent at cols. 11-12).

Systematic administration may also be realized by a second method of achieving effective anxiolytic blood levels of [the 6-hydroxy-metabolite] which is to orally administer a precursor form of [the 6-hydroxy-metabolite]. Such prodrug forms would be administered in dosage amounts that would produce effective anxiolytic effects without causing harmful or untoward side-effects. That is, systematic administration of [the 6-hydroxy-metabolite] may be accomplished by oral administration of a precursor or prodrug form of [the 6-hydroxy-metabolite], e.g., buspirone, to mammals.

However, this method of systematic introduction of [the 6-hydroxy-metabolite] improves upon and differs from the known standard method of oral administration of buspirone. . . . in contradiction to currently accepted methods of administration that are directed to maximizing blood levels of unchanged buspirone . . . directly counter to the past method of orally administering buspirone.

'365 Patent, *supra* note 18.

body.”<sup>57</sup> The technical meaning of terms is presumed to be used for reliability and familiarity purposes with those experienced in the area.<sup>58</sup>

### *The Prosecution History*

The prosecution history also foreclosed the possibility that the ‘365 Patent covers uses of buspirone.<sup>59</sup> Bristol-Myers repeatedly attempted to obtain a patent that covered uses of buspirone and the Patent Examiner consistently rejected this request.

Bristol-Myers first application, the ‘842 Application, on its face claimed both the 6-hydroxy-metabolite and a prodrug thereof.<sup>60</sup> When Bristol-Myers applied to make the ‘842 Application special to expedite its processing, the Patent Examiner required that Bristol-Myers restrict the application to one of two distinctly patentable inventions. Bristol-Myers elected to pursue a patent limited to the prodrug of the 6-hydroxy-metabolite, i.e. buspirone, rather than to the 6-hydroxy-metabolite itself. The Patent Examiner then rejected the narrowed ‘842 Application under 35 U.S.C. Section 102(b) and 35 U.S.C. Section 103(a) because such uses of buspirone were covered by an on sale bar in view of the prior sales of Buspar® and were obvious in light of the prior art of buspirone uses. The Patent Examiner notified Bristol-Myers that the non-elected subject matter could later be claimed in a divisional application.<sup>61</sup>

Bristol-Myers then filed an application, the ‘161 Divisional Application, claiming the non-elected subject matter of the ‘842 Application,<sup>62</sup> the 6-hydroxy-metabolite.

Shortly after the filing of the ‘161 Divisional Application, Bristol-Myers filed four more

---

<sup>57</sup> 185 F. Supp. 2d at 353.

<sup>58</sup> See *Hoechst Celanese Corp. v. BP Chem. Ltd.*, 78 F.3d 1575, 1581 (Fed. Cir. 1996).

<sup>59</sup> See 185 F. Supp. 2d at 359.

<sup>60</sup> See *id.* at 340 (citing U.S. Patent Application No. 09/368,842).

<sup>61</sup> See 35 U.S.C. § 121 (describing requirements for divisional applications).

patent applications, each of which were CIPs of the ‘161 Divisional Application.<sup>63</sup> The Patent Examiner then rejected two of the applications under 35 U.S.C. Section 102(b) and 35 U.S.C. Section 103(a) for the same reasons set forth in the rejection of the ‘842 Application. Rejection of the remaining three applications was premised on provisional double patenting grounds since identical claim language was used. To remedy this problem, Bristol-Myers abandoned all applications except the ‘211 CIP Application. The ‘211 CIP Application was expedited and eventually led to issuance of the ‘365 Patent claiming the 6-hydroxy-metabolite, but neither buspirone nor any prodrug thereof.<sup>64</sup>

This history indicates Bristol-Myers narrowed its application only to uses of the 6-hydroxy-metabolite of buspirone, and is thereby estopped from extending the scope of the ‘365 Patent to cover uses of buspirone itself.<sup>65</sup> Furthermore, the Federal Circuit Court of Appeals has held that although claims in divisional applications may be amended, “they must not be so amended as to bring them back over the line imposed in the restriction requirement.”<sup>66</sup>

*35 U.S.C. Section 102(b)*

Mylan and Watson correctly argued that the ‘365 Patent would be invalid if construed to cover uses of buspirone based on 35 U.S.C. Section 102(b). The use of buspirone to treat anxiety was the subject of a previously issued patent (the ‘763 Patent). Also, the use of buspirone was described in a printed publication (the FDA-approved

---

<sup>62</sup> See 185 F. Supp. 2d at 347 (citing U.S. Patent Application No. 09/484,161).

<sup>63</sup> See *id.* at 340 (citing U.S. Patent Application Nos. 09/588,221, 09/588,222, 09/588,223 and 09/588,220).

<sup>64</sup> See *id.* at 343 (citing U.S. Patent No. 6,150,365 (issued Nov. 21, 2000)).

<sup>65</sup> *Id.* at 359.

<sup>66</sup> See *Gerber Garment Technology, Inc. v. Lectra Systems, Inc.*, 916 F.2d 683, 688 (Fed. Cir. 1990).

labeling instructions for Buspar®) and was “in public use in [the United States] more than one year prior to the date that on which Bristol-Myers applied for the ‘365 Patent.”<sup>67</sup> These facts are alone sufficient to decide the issue of invalidity.<sup>68</sup>

Bristol-Myers asserted that in order for a prior invention to raise a statutory bar under this section, the prior invention must disclose each claim limitation of the claimed invention, either explicitly or inherently.<sup>69</sup> The Federal Circuit Court of Appeals explained that a claim is anticipated, regardless of whether it also covers subject matter not in the prior art, if the disputed claim would exclude the public from practicing the prior art.<sup>70</sup> Therefore, Bristol-Myers argument that the ‘365 Patent covers uses of buspirone is misplaced.

United States District Judge John G. Koeltl granted summary judgment in favor of Mylan and Watson finding that the ‘365 Patent does not cover uses of buspirone.<sup>71</sup> The court next considered Bristol-Myers motion to dismiss the antitrust counterclaims brought in response to Bristol-Myers alleged inequitable conduct.

#### History: In re Buspirone Antitrust Litigation<sup>72</sup>

Along with the patent disputes discussed above, the Judicial Panel for Multidistrict Litigation had consolidated twenty-two antitrust actions brought by various generic drug manufacturers who seek to enter the buspirone market, direct purchasers of

---

<sup>67</sup> 185 F. Supp. 2d at 360.

<sup>68</sup> *Id.*

<sup>69</sup> See *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

<sup>70</sup> See *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999).

<sup>71</sup> See *In re Buspirone Patent Litigation*, 185 F. Supp. 2d 363, 367, 2002-1 Trade Cases P 73,596 (citing *In re Buspirone*, MDL No. 1410, slip op. at 6-26 (S.D.N.Y. Feb. 14, 2002) (Order No. 18) (Motion for Summary Judgment on Patent Infringement Claims)).



buspirone products, end-payers who have purchased buspirone, consumer protection organizations, and thirty states.<sup>73</sup>

Some of the complaints allege that Bristol-Myers attempted to extend or extended an unlawful monopoly over buspirone products for use in the treatment of anxiety.

Complaints also allege Bristol-Myers entered into a conspiracy to restrain trade in this market, thereby violating sections 1 and 2 of the Sherman Act,<sup>74</sup> by settling a patent infringement suit with Danbury Pharmacal, Inc., and its affiliate Schein Pharmaceuticals, Inc. These plaintiffs also allege that Bristol-Myers' settlement, in which Schein agreed to stay out of the buspirone market, was a sham to cover the invalidity of the '763 Patent.<sup>75</sup>

All of the complaints allege that Bristol-Myers attempted to extend or extended an unlawful monopoly over the buspirone market in violation of section 2 of the Sherman Act,<sup>76</sup> by abusing a number of provisions of the Hatch-Waxman Amendments,<sup>77</sup> known as the Drug Price Competition and Patent Term Restoration Act. These complaints allege: that Bristol-Myers listed a new patent (the '365 Patent) in the Orange Book less than one day before the '763 Patent was set to expire, that Bristol-Myers fraudulently asserted to the FDA that the '365 Patent covered uses of buspirone and that patent

---

<sup>72</sup> *Id.* at 363.

<sup>73</sup> *Id.* at 365.

<sup>74</sup> *See* 15 U.S.C. §§ 1-2 .

<sup>75</sup> *See* 185 F. Supp. 2d at 366.

<sup>76</sup> *See* 15 U.S.C. § 2.

<sup>77</sup> "If the applicant made a certification described in sub clause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless an action is brought for infringement of a patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. If such an action is brought before the expiration of such days, the approval 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) or such shorter or longer period

infringements suits could be brought against generic producers of buspirone, and that Bristol-Myers immediately brought the patent infringements suits, triggering an automatic stay for up to thirty months of the generic manufacturer's approval of their respective products.<sup>78</sup> Bristol-Myers moved pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss all of the claims raised by the antitrust plaintiffs.<sup>79</sup>

### The Conclusion

United States District Judge John G. Koeltl held that Bristol-Myers was not entitled to Noerr-Pennington immunity in its listing of the '365 Patent with the FDA,<sup>80</sup> and "if the Noerr-Pennington doctrine were to apply . . . Mylan and Watson have pleaded sufficient facts to warrant an exception to the immunity."<sup>81</sup> Therefore, Bristol-Myers' motion to dismiss the antitrust claims was denied.<sup>82</sup>

As mentioned above, Noerr-Pennington immunity shields efforts to influence the legislature or the executive to take particular action from antitrust sanctions.<sup>83</sup> There are two ways to lose Noerr-Pennington immunity: 1) if the patent in issue was obtained through knowing and willful fraud and the plaintiff is aware of the fraud when bringing subsequent patent infringement suits;<sup>84</sup> or, 2) if the subsequent patent infringement suits

---

as the court may order because either party to the action failed to reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>78</sup> 185 F. Supp. 2d at 366.

<sup>79</sup> See *id.*

<sup>80</sup> *Id.* at 372.

<sup>81</sup> *Id.* at 373.

<sup>82</sup> *Id.* at 380.

<sup>83</sup> See *Noerr*, 365 U.S. at 127; *Pennington*, 381 U.S. at 657.

<sup>84</sup> See 185 F. Supp. 2d at 374-75. See also *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965).

were a mere sham to interfere with the business of a competitor through use of the governmental process.<sup>85</sup>

Judge Koeltl reasoned that Noerr-Pennington immunity, which protects petitioning activity, does not apply to Bristol-Myers' Orange Book listing of the '365 Patent. Petitioning conduct for Noerr-Pennington purposes applies in situations where the governmental entity renders a decision only after an independent review of the merits of a petition. Since the FDA acts in a ministerial or non-discretionary fashion in its listing of ANDAs in the Orange Book, the Noerr-Pennington doctrine was not applicable to such conduct.<sup>86</sup>

Assuming the Noerr-Pennington doctrine were to apply to Bristol-Myers' Orange Book listing, Mylan and Watson had pleaded sufficiently to establish the *Walker Process* exception.<sup>87</sup> *Walker Process* involved a fraudulent misrepresentation to the patent examiner in prosecuting a patent application.<sup>88</sup> Judge Koeltl, noting that this was a question of first impression under federal circuit law (alleged fraudulent enlargement of the asserted scope of a patent before the FDA), reasoned that since a fraudulent misrepresentation to the patent examiner can effectively extend a monopoly, a fraudulent listing in the Orange Book, which can also effectively extend a monopoly, should be subject to the *Walker Process* exception as well.<sup>89</sup>

---

<sup>85</sup> See *Prof'l Real Estate Investors Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49 (1993).

<sup>86</sup> See 185 F. Supp. 2d at 369.

<sup>87</sup> *Id.* at 373.

<sup>88</sup> See *Walker Process*, 382 U.S. 172 (1965).

<sup>89</sup> See 185 F. Supp. 2d at 374 (citing *Warner-Lampert Co. v. Purepac Pharms., Co.*, No. 99-5948, slip op., at 11-13 (D.N.J. Dec. 22, 2000)(holding that fraudulent listing in Orange Book is subject to *Walker Process* exception to Noerr-Pennington immunity)).

Further assuming that Noerr-Pennington immunity applies to Bristol-Myers listing with the FDA, and that the *Walker Process* exception to this immunity does not apply, Mylan and Watson pleaded sufficiently for the *Professional Real Estate Investors* exception to apply.<sup>90</sup> *Professional Real Estate Investors* formulates an exception to Noerr-Pennington immunity for lawsuits that are a mere “sham.” “Sham” lawsuits contain an objective and subjective component. A lawsuit is “objectively baseless if ‘no reasonable litigant could realistically expect success on the merits.’”<sup>91</sup> The subjective component is satisfied when the “baseless lawsuit conceals ‘an attempt to interfere directly with the business relationships of a competitor’ through the ‘use of the governmental process - as opposed to the outcome of that process - as an anticompetitive weapon’”.<sup>92</sup> Based on Bristol-Myers’ repeated attempts to obtain a patent covering uses of buspirone and the Patent Examiner’s repeated denial of such a patent, Judge Koeltl concluded that Bristol-Myers had no objective basis for believing that the ‘365 Patent covered uses of buspirone or that the patent would be valid if it did.”<sup>93</sup> The antitrust plaintiffs alleged that Bristol-Myers listed with the FDA solely to stall the approval of Mylan’s and Watson’s respective ANDAs for up to thirty months, knowing that its claims lacked merit.<sup>94</sup> This knowledge was sufficient to satisfy the subjective element of the “sham” exception for purposes of withstanding a motion to dismiss.<sup>95</sup>

---

<sup>90</sup> *Id.* at 375.

<sup>91</sup> *Id.* at 375 (quoting *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49, 60 (1993)).

<sup>92</sup> *Prof'l Real Estate Investors*, 508 U.S. 49, 60-61 (1993) (quoting *Noerr, supra* note 3 and *City of Colombia v. Omni Outdoor Adver., Inc.*, 499 U.S. 365, 380 (1991)).

<sup>93</sup> 185 F. Supp. 2d at 376.

<sup>94</sup> *Id.* at 376, n. 5.

## Analysis

To strike a balance between the interests of pioneer researchers and generic drug manufacturers, the “Hatch-Waxman” amendments to the Federal Food, Drug and Cosmetic Act were added to the Drug Price Competition and Patent Term Restoration Act of 1984.<sup>96</sup> Congress attempted to induce pioneer research and development of new drugs, while simultaneously enabling competitors to bring low cost generic versions of these drugs into the market.<sup>97</sup>

### The Hatch-Waxman Amendments

The Hatch-Waxman amendments permit generic drug manufacturers to engage in what would otherwise be considered infringing conduct during the term of a pioneer drug’s patent in order to obtain regulatory approval of their generic drugs without fear of patent infringement actions brought by the pioneer patent holder.<sup>98</sup> In other words, generic drug manufacturers can use the generic drug products to raise capital, obtain foreign patents, and can even ship the generic products to potential commercial partners, all in order to have FDA approval for generic sale obtained prior to the day when the pioneer patent holder’s drug is set to expire.<sup>99</sup>

The generic drug manufacturer submits an ANDA and is required to address each patent previously listed in the Orange Book that claims the drug. The ANDA applicant must certify that no patent information concerning this drug has ever been submitted to

---

<sup>95</sup> See *id.* at 380.

<sup>96</sup> 21 U.S.C. § 355.

<sup>97</sup> *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1370-71 (Fed. Cir. 2002).

<sup>98</sup> See Brian D. Coggio, *The Application of the Patent Laws to the Drug Approval Process*, 52 FOOD DRUG L.J. 345, 346 (1997).

<sup>99</sup> *Id.* at 347.

the FDA (paragraph I certification). If a patent exists, the applicant must certify that the patent has expired (paragraph II certification), the patent is set to expire on a certain date (paragraph III certification), or that the patent is invalid or will not be infringed by the manufacture, use, or sale of the new generic drug for which the ANDA is submitted (paragraph IV certification).<sup>100</sup>

When an ANDA contains a paragraph IV certification, the applicant (generic drug manufacturer) must give notice to the holder of the alleged invalid patent (pioneer patent holder) describing its belief why manufacture, use, or sale of the generic version of the drug by the generic drug manufacturer will not infringe the pioneer patent holder's issued patent.<sup>101</sup> The pioneer patent holder then has a forty-five day period in which to bring patent infringement lawsuits against the generic drug manufacturer. If such lawsuits are brought, the FDA is required to stay the generic drug manufacturers ANDA approval for the lesser of thirty months or until the relevant patent disputes are resolved. The court in which the suit is pending may order a shorter or longer stay if "either party to the action fails to reasonably cooperate in expediting the action."<sup>102</sup>

Prior to this decision, Mylan had brought suit against Bristol-Myers, the FDA, and the Secretary of Health and Human Services attempting to "delist" the '365 Patent from the Orange Book.<sup>103</sup> The Court of Appeals for the Federal Circuit held that neither the patent laws nor the Hatch-Waxman amendments permitted a private right of action to "delist" a patent from the Orange Book.<sup>104</sup> In *Andrx Pharmaceuticals v. Biovail*

---

<sup>100</sup> *Andrx*, 276 F.3d at 1368 (citing 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV)).

<sup>101</sup> 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

<sup>102</sup> 21 U.S.C. § 355(j)(5)(B)(iii).

<sup>103</sup> *See Mylan Pharms.*, 268 F.3d 1323.

<sup>104</sup> *Id.* at 1333.

*Corporation*, the Federal Circuit later stated that they were not holding that the FDA could not be directly be sued to compel them to approve an ANDA if their denial of the ANDA was arbitrary or capricious.<sup>105</sup>

Applying the Federal Circuit's interpretation of the Hatch-Waxman amendments to the case at hand and the case law relating to the delisting of a patent, several important aspects of the conduct of Bristol-Myers and Mylan and Watson can be analyzed. First, it can be seen that generic drug manufacturers and pioneer patent holders each receive benefits and disadvantages from a practical standpoint from the Hatch-Waxman amendments, and second, the presence of the Hatch-Waxman amendments is what triggers the antitrust consequences relating to Bristol-Myers conduct.

#### *Advantages and Disadvantages of the Hatch-Waxman Amendments*

The Hatch-Waxman amendments were designed to give generic drug manufacturers (Mylan and Watson) the benefit of engaging in otherwise infringing conduct during the unexpired term of a pioneer patent holders (Bristol-Myers) patent.<sup>106</sup> However, while giving the generic drug manufacturers an opportunity to get a "head-start" on approval for the manufacture, use or sale of generic drugs, the generic drug manufacturer's head-start can effectively be negated by the pioneer patent holders listing of an existing patent that arguably bars the sale of the generic drug manufacturers drug.

---

<sup>105</sup> See *Andrx*, 276 F.3d at 1378.

<sup>106</sup> See *id.* at 1371.

According to *Andrx*, the generic drug manufacturers would have to meet the almost insurmountable burden of showing that the refusal to issue the ANDA by the FDA was either arbitrary or capricious.<sup>107</sup>

However, *Andrx*'s "complaint did not allege that any of the claims arose under the APA or that the FDA had acted arbitrarily, capriciously, or not in accordance with law in denying approval of the ANDA."<sup>108</sup> "Moreover, the district court found that *Andrx*'s 'Amended Complaint does not list a specific count alleging any wrongdoing by the Federal Defendants, and therefore dismissed the federal defendants from this action.'"<sup>109</sup> That dismissal is not challenged on this appeal. An APA claim can hardly lie when the government is no longer a party to the action. Furthermore, that burden exists along with the fact that the FDA, in a ministerial fashion, is not exercising any discretion in whether or not to list the pioneer patent holders patent.<sup>110</sup> One commentator suggests that a pioneer patent holder could keep filing with the FDA in order to receive unlimited consecutive thirty month stays (which, by law, the FDA is required to execute), since a generic drug manufacturer has little or no capacity to remove the listing.<sup>111</sup>

Subsequent to listing in the Orange Book, the FDA is required by law upon the filing of corresponding patent infringement lawsuits by a pioneer patent holder to issue a

---

<sup>107</sup> *See id.* at 1379

<sup>108</sup> *Id.* at 1380.

<sup>109</sup> *Id.* at 1380 (quoting *Andrx*, 276 F.3d at 1367 (citing Amended Complaint, ¶¶ 55-58), vacated by 276 F.3d 1368 (2002)).

<sup>110</sup> *See* 185 F. Supp. 2d at 371.

<sup>111</sup> *See* Terry G. Mahn, *Symposium Issue -- Striking The Right Balance Between Innovation And Drug Price Competition: Understanding The Hatch-Waxman Act: Patenting Drug Products: Anticipating Hatch-Waxman Issues During the Claims Drafting Process*, 54 FOOD DRUG COSM. L.J. 245, 250 (1999).



thirty-month stay until these disputes are settled.<sup>112</sup> The Hatch-Waxman amendments thus also give pioneer drug manufacturers the opportunity to protect their patent rights by listing with the FDA and effectively stopping the progress of ANDA approval.<sup>113</sup> As a consequence stemming from this listing, the United States District Court for the Southern District of New York in the case at hand holds that the issuance of an automatic stay by the FDA can sometimes trigger antitrust consequences against the party activating the stay.<sup>114</sup>

The Hatch-Waxman amendments create the probable scenario that, in the normal course of events, a generic drug manufacturer will submit an ANDA to the FDA seeking approval of their generic drug, and a pioneer patent holder will have the opportunity to then halt approval by listing a patent of their own that allegedly bars the sale of the generic version. Since a generic drug manufacturer is unlikely able to delist a patent submitted by a pioneer patent holder, an automatic thirty-month stay would be activated.<sup>115</sup> According to the case at hand, the pioneer patent holder will always be subject to the assertion of an antitrust counterclaim occurring from the application of the mandatory stay.

Several inquiries into possible antitrust litigation involving this course of events are appropriate. By analyzing the elements of the antitrust claim, it can be seen that an antitrust defendant may be able to avoid antitrust consequences altogether depending on their course of conduct, even if they list with the FDA and trigger an automatic stay. Additionally, the difficulty of proving an antitrust violation can be seen to enormously

---

<sup>112</sup> *Id.* at 250.

<sup>113</sup> *See generally Andrx.*

<sup>114</sup> *See* 185 F. Supp. 2d at 372, 373.

differ, from almost trivial to nearly impossible, depending on the course of conduct taken by the antitrust defendant, regardless of their underlying subjective motivation.

*Alternative Courses of Conduct Available to a Pioneer Patent Holder*

To prove a violation of the antitrust laws, an antitrust plaintiff must prove that Noerr-Pennington immunity does not apply. If Noerr-Pennington does not apply, the patent infringement lawsuit brought by the pioneer patent holder is a “sham.”<sup>116</sup> Sham litigation contains both an objective and subjective element: “The lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits.”<sup>117</sup> This objectively baseless lawsuit must conceal an attempt to interfere with the business of a competitor through the use of the governmental process, as opposed to the outcome of the process, as an anticompetitive weapon.<sup>118</sup> In the *Buspirone Patent Litigation*, the court held that “the positions that Bristol-Myers has taken with regard to the scope of the patent and whether Mylan’s and Watson’s products infringe the patent are objectively baseless.”<sup>119</sup> For the purposes of this analysis, the author will assume the court’s decision that the claim is objectively baseless is accurately based in law. If the patent infringement lawsuit is not objectively baseless, no subjective inquiry is necessary because the Noerr-Pennington doctrine protects the pioneer patent holders’ conduct.

---

<sup>115</sup> See generally *Andrx*.

<sup>116</sup> See *Prof'l Real Estate Investors*, 508 U.S. at 60.

<sup>117</sup> *Id.* at 60-61.

<sup>118</sup> *Id.*

<sup>119</sup> 185 F. Supp. 2d at 375.

In the *Buspirone Patent Litigation*, Judge Koeltl stated that Bristol-Myers did not necessarily have to list with the FDA in order to seek a remedy; Bristol-Myers could have alternatively filed a patent infringement lawsuit in federal court and sought a preliminary injunction stopping FDA approval of Mylan and Watson's generic drugs.<sup>120</sup> This alternative pathway would not trigger an automatic stay, since a preliminary injunction may be granted at the discretion of the court. Bristol-Myers's conduct would then be protected under the Noerr-Pennington doctrine as petitioning activity. Mylan and Watson would then not be permitted to prove that Bristol-Myers had the requisite subjective motivation to interfere with their businesses in such a manner.

Although his reasoning is sound, such an alternative course of conduct may not be in the best interests of a pioneer patent holder. Hypothetically, before listing with the FDA, a pioneer patent holder may believe that their patent infringement claims are not objectively baseless. The patent holder would then have no reason to seek a preliminary injunction from a federal court since they could obtain an automatic stay from the FDA, by simply listing the patent.

Similarly, if a pioneer patent holder believes that their patent infringement claims have merit and if a court finds that the claims do indeed have merit, it is irrelevant if the pioneer patent holder had an intent to interfere with the business of a competitor, as a subjective inquiry is not proper if the patent infringement claims are not objectively baseless.<sup>121</sup> For example, a pioneer patent holder may have a meritorious lawsuit that would not be economically advantageous to bring from a patent rights perspective. Nevertheless, this pioneer patent holder may bring the lawsuit seeking to interfere with

---

<sup>120</sup> *Id.* at 372.

the business of a competitor through use of the governmental process. Furthermore, the patent holder will be shielded from antitrust liability if their lawsuit is determined not to be objectively baseless, even if they had a realistic expectation of success on the merits. Such a situation would permit a pioneer patent holder to interfere with the business of a competitor without regard to antitrust consequences.

On the other hand, if a pioneer patent holder's patent infringement claims are determined to be objectively baseless, since even if the pioneer patent holder believed them to be meritorious, the requisite showing of subjective motivation to interfere with a competitor's business through the use of the governmental process is satisfied because the pioneer patent holder had the intent to interfere based upon their conduct. Even if the pioneer patent holder did not have the intent to interfere, they would still have to defend allegations of such intent, which could prove costly and time consuming, and generate negative publicity. In contrast to the aforementioned situation, currently a pioneer patent holder would be subject only to antitrust consequences, even though in both situations there existed an identical intent to interfere with the business of a competitor.

Since *In re Buspirone Patent Litigation* demonstrates that it is possible for antitrust counterclaims to succeed, a pioneer drug manufacturer will have to think twice about the merit of their lawsuit before listing with the FDA.

#### *An Antitrust Plaintiff's Evidentiary Burden after a Defendant's Listing with the FDA*

Such an anomalous situation creates uncertainty because a number of possible circumstances exist. Firstly, if a pioneer patent holder believes that they have an

---

<sup>121</sup> See *Prof'l Real Estate Investors*, 276 F.3d at 60.

objectively meritorious lawsuit lists with the FDA and brings infringement claims with an intent to interfere with the business of a competitor through the governmental process itself, the patent holder is shielded from antitrust liability because her lawsuit is not objectively baseless.

On the other hand, if a pioneer patent holder's lawsuit were determined by a court to be objectively baseless, a generic drug manufacturer would have the opportunity to examine the subjective motivation of the patent holder. In some instances, it may be extremely difficult to establish evidentiary proof of a subjective motivation to interfere because relevant evidence is most likely in the hands of the pioneer patent holder.

Evidence of such interference cannot be determined circumstantially because a specific showing of subjective intent is required. In the case at hand, even though Bristol-Myers obtained the '365 Patent only one day before expiration of the '763 Patent, the Patent Examiner repeatedly refused to issue a patent covering uses of buspirone and Judge Koeltl found no objective claim of infringement, Mylan and Watson are still required to come forth with concrete evidence of Bristol-Myers' subjective motivation to interfere. Although this motivation seems to have existed based on the circumstances, Mylan and Watson, as well as any future antitrust plaintiff, may find proving this motivation difficult.

Bristol-Myers may have acted for tactical purposes. Bristol-Myers, benefiting from its success in the pharmaceutical industry, has the luxury of being able to afford the best legal advice, as well as the financial ability to settle disputes. It can safely be assumed that Bristol-Myers was likely fully aware of the relevant case law that establishes the principle that patents for metabolites do not bar the use of their

prodrugs.<sup>122</sup> In light of this assumption, Bristol-Myers may have obtained the ‘365 Patent with the intent to wield it as a weapon used to pressure competitors to stay out of the buspirone market.<sup>123</sup> If these settlement agreements were unsuccessful, Bristol-Myers may have believed that they would suffer no loss, except the emergence of competition in the buspirone market. Prior to the current case, no existing case law dealt with the issue of whether antitrust consequences could arise from a pioneer patent holder’s listing with the FDA.

If Mylan and Watson can prove that Bristol-Myers had the requisite subjective intent to interfere with their businesses through use of the governmental process, *In re Buspirone* would open the door for antitrust counterclaims. Similarly, powerful pharmaceutical companies would no longer be able to outspend smaller pharmaceutical companies to force a settlement because smaller pharmaceutical companies would have the confidence necessary to assert antitrust counterclaims if there is a hint of inequitable conduct.

---

<sup>122</sup> See *Hoechst-Roussel v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997) (holding that patents for metabolites do not cover their prodrugs); *Atlas Powder Co. v. Ireco, Inc.*, 190 F.3d 1342 (Fed. Cir. 1999) (holding that the patentee attempted to patent the unpatentable, i.e. a scientific explanation); *In re Omeprazole Patent Litigation*, No. MDL 1291, 2001 U.S. Dist. LEXIS 7103 (S.D.N.Y. 2001) (holding that a sulphenamide (similar to a metabolite) is inherently disclosed in the prior art).

<sup>123</sup> In 1994, Bristol-Myers entered into a settlement agreement with Danbury Pharmacal, Inc., and its affiliate Schein Pharmaceuticals, where Danbury and Schein agreed to stay out of the buspirone market in return for \$72.5 million dollars. Mylan and Watson allege that this settlement was a sham to cover up the invalidity of the ‘763 Patent. See 185 F. Supp. 2d at 366.

Similarities Between the Professional Real Estate Exception and the Walker Process  
Exception to Noerr-Pennington Immunity

To prove a violation of the antitrust laws when the patent in question is fraudulently obtained and subsequently enforced through patent infringement lawsuits brought against competitors, a plaintiff must prove that Noerr-Pennington immunity does not apply. In *Walker Process*, Justice Harlan stated in his concurrence that antitrust consequences would apply to conduct where a party knowingly and willfully made false representations to the government in order to obtain a patent.<sup>124</sup> In *Buspirone*, Judge Koeltl, noting the issue to be one of first impression under Federal Circuit law, held that the *Walker Process* exception applies to an alleged fraudulent patent listing with the FDA.<sup>125</sup>

Judge Koeltl stated that the Supreme Court in *Walker Process* explained that a fraud on the FDA would result in the loss of Noerr-Pennington immunity for reasons that are applicable to fraudulent listings with the Patent Office.<sup>126</sup> Since a pioneer patent holder can effectively extend its monopoly by listing with the FDA, the same considerations in *Walker Process* are applicable to such a listing.<sup>127</sup>

The Federal Circuit should uphold Judge Koeltl's extension of the *Walker Process* exception to listing with the FDA, since the *Walker Process* exception

---

<sup>124</sup> See *Walker Process*, 382 U.S. at 179 (Harlan, J., concurring).

<sup>125</sup> 185 F. Supp. 2d at 374.

<sup>126</sup> “[A] patent by its very nature is affected with a public interest. . . . It is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.” *Walker Process*, at 177 (quoting *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 816 (1945)).

(fraudulent misrepresentations to the FDA) and the *Professional Real Estate Investors* exception (“sham” lawsuits arising out of listing with the FDA) to Noerr-Pennington immunity are based upon similar criteria.

To warrant an exception to Noerr-Pennington immunity under *Walker Process*, an antitrust plaintiff in a patent infringement lawsuit must show that the patent in question was fraudulently procured. This requires a showing that the antitrust defendant acted with deliberate fraud, i.e., that the antitrust defendant knowingly and in a fraudulent manner made false representations of fact to the Patent Office in the prosecution of a patent.<sup>128</sup> Therefore, the *Walker Process* exception comprises two elements, false representation of fact (objective element) and fraudulent intent (subjective element).

Similarly, the *Professional Real Estate Investors* “sham” litigation exception to Noerr-Pennington immunity comprises two elements, objective baselessness (objective element) and fraudulent intent (subjective element). Virtually identical proof is necessary to satisfy the subjective element under both *Walker Process* and *Professional Real Estate Investors*. In addition, a factual showing of objective baselessness under *Professional Real Estate Investors* is essentially equivalent to a showing of false representations of fact under *Walker Process*.

A false representation of fact to the Patent Office and an objectively baseless lawsuit contain similar components. A false representation of fact supports a patent that should not have been issued, and an objectively baseless lawsuit supports a lawsuit that should not have been brought. Once it is objectively determined that there was a misrepresentation of fact, and once it is objectively determined that a lawsuit is baseless,

---

<sup>127</sup> See 185 F. Supp. 2d at 374.



subjective inquiries into the intent of the antitrust defendant are warranted. Therefore, the *Walker Process* exception and the *Professional Real Estate Investors* exception involve essentially identical analyses.

---

<sup>128</sup> See *Walker Process*, 382 U.S. at 179 (Harlan, J., concurring).