



## DEVELOPMENTS IN PATENT LAW 2003

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### ABSTRACT

The year 2003 provided a great deal of legislative, administrative and judicial activity in the development of patent law. Legislation has been directed to amending the Hatch-Waxman Act and abrogation of State immunity from patent infringement. The U.S. Patent and Trademark Office has adopted changes pursuant to recent amendments to the Patent Cooperation Treaty and implemented an electronic filing system for patent applications. The Federal Trade Commission has taken an interest in patents, particularly standard setting technologies. In light of the Supreme Court's decision in *Festo*, the Federal Circuit has provided additional guidance for prosecution history estoppel and the doctrine of equivalents. This article summarizes these and other developments, and provides recommendations to patent practitioners on how to operate with these new and exciting developments.

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## DEVELOPMENTS IN PATENT LAW 2003

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### I. LEGISLATIVE DEVELOPMENTS

#### A. *Medicare Prescription Drug Improvement and Modernization Act of 2003*

This Act is included in Title XI, Section 1101–1104 of the Medicare Prescription Drug Improvement and Modernization Act of 2003.<sup>1</sup> Section 1101 of the Act amends the Hatch-Waxman Act,<sup>2</sup> which sets requirements for an Abbreviated New Drug Application (“ANDA”) to be filed with the FDA. Under Hatch-Waxman, ANDA applicants (usually generic drug companies) may rely on the safety and effectiveness data contained in an original New Drug Application (“NDA”) if the ANDA applicant shows that the active ingredients in the proposed drug are the same as the active ingredients in the previously approved NDA and the proposed drug is bioequivalent to the approved drug.<sup>3</sup>

An NDA applicant must identify any patent that claims the drug or a method of using the drug.<sup>4</sup> The FDA then lists these patents in its “Orange Book.” The NDA applicant must file for listing in the Orange Book any pertinent patents that issued after the NDA is approved.<sup>5</sup>

The new law amends the statute by prohibiting an ANDA applicant from amending or supplementing its application to seek approval of a drug different from the listed drug identified in the original ANDA.<sup>6</sup> However, this prohibition does not apply if the amendment or supplement only seeks approval of a different strength for the drug in the original ANDA.<sup>7</sup> Under this new provision, the FDA must issue a definition of the term “listed drug.”

Under the old law, an ANDA applicant had to certify in its application, for each patent listed in the Orange Book, one of four grounds for avoiding infringement liability.<sup>8</sup> One ground was that the patent “is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted.” If the ANDA applicant

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<sup>1</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

<sup>2</sup> Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984)

<sup>3</sup> 21 U.S.C. § 355(j)(A) (2003).

<sup>4</sup> *Id.* § 355(b)(1) (2003).

<sup>5</sup> *Id.* § 355(c)(2) (2003).

<sup>6</sup> *Id.* § 355(j)(2)(D)(i) (2003).

<sup>7</sup> *Id.* § 355(j)(2)(D)(ii) (2003).

<sup>8</sup> *Id.* § 355(j)(2)(A)(vii)(I)–(IV) (2003).

relies upon this certification, it must notify the patent owner and the owner of the approved NDA application.<sup>9</sup> No time limit was specified for providing this notice.

Under the new law, notice must be given (1) if the certification is in the ANDA, within 20 days of receiving notice from the FDA that the ANDA has been filed, or (2) if the certification is in an amendment or supplement to the ANDA, at the time such amendment or supplement is filed.<sup>10</sup> Once the patent holder receives this notice, the patent owner is given 45 days to file a patent infringement suit against the ANDA applicant.<sup>11</sup> The filing of the certification constitutes an infringing act.<sup>12</sup>

More importantly, the new law limits the 30-month stay period provided by 21 U.S.C. § 355(j)(5)(B)(iii). Under the old law, if a patent owner filed an infringement suit within the 45-day period, the FDA was prohibited from approving the ANDA until 30 months from the date the applicant notified the patent owner of the application. Under the new law, the 30-month stay applies only to patents listed in the Orange Book before a “substantially complete” ANDA is filed.<sup>13</sup>

The new law also clarifies when the 30-month stay ends. Under the old law, the stay would end if, before expiration of this period, (1) the court held the patent invalid or not infringed, in which case the ANDA approval would become effective on the date of the court decision. Under the new law, the stay period is determined by the following rules:

- (1) if, before expiration of the 30-month stay, the district court holds the patent invalid or not infringed, the approval becomes effective on either the date the court enters judgment or the date a settlement order or consent decree is signed and entered by the court, stating that the patent is invalid or not infringed;
- (2) if, before expiration of the 30-month period, the court rules that the patent has been infringed and, if the judgment is appealed, the approval becomes effective on the date on which the appeals court decides the patent is invalid or not infringed or the date a settlement order or consent decree is entered by the appeals court stating that the patent is invalid or not infringed;
- (3) finally, if, before expiration of the 30-month period, the court rules that the patent is infringed and the judgment is not appealed or affirmed, the approval becomes effective on the date specified by the district court under 35 U.S.C. § 271(e)(4)(A).<sup>14</sup>

These changes to the law were prompted by alleged abuses of the 30-month stay provisions, wherein certain pharmaceutical companies would add new patents to existing drug applications, prompting the generic competitors to file additional certifications for those patents, which in turn prompted the pharmaceutical companies to file additional lawsuits, leading to new 30-month stays of FDA approval for the same drug. These

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<sup>9</sup> *Id.* § 355(j)(2)(B) (2003).

<sup>10</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

<sup>11</sup> *Id.*

<sup>12</sup> 35 U.S.C. § 271(e)(2)(A) (2002).

<sup>13</sup> *See* 21 U.S.C. § 355(j)(5)(B)(iii) (2003).

<sup>14</sup> Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

maneuvers had the effect of prolonging the period of time before which generic drugs could be brought to market.

The new legislation also permits an ANDA applicant to file a declaratory judgment action if (1) the 45-day period has expired without the patent owner suing for infringement after receiving a certification, and (2) if the certification asserts noninfringement, the notice must include an offer of confidential access to the ANDA for the purpose of determining whether an action or infringement should be filed.<sup>15</sup>

*B. Appropriations for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies for the Fiscal Year Ending September 30, 2004*

This Act contains a provision stating that “[n]one of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism.”<sup>16</sup>

*C. Intellectual Property Protection Restoration Act of 2003*

This bill would apply the patent statutes (as well as the copyright and trademark statutes) to “abrogate State sovereign immunity in cases where States or their instrumentalities, officers or employees” infringe any of these statutes.<sup>17</sup> To accomplish this, 35 U.S.C. § 287 would be amended to include a new section providing that a state or state instrumentality would not be entitled to any remedies for patent infringement under 35 U.S.C. § 284 (utility patents) or 35 U.S.C. § 289 (design patents), absent proof that the state has waived its Eleventh Amendment immunity from suit for infringement of any federal intellectual property law.<sup>18</sup> This limitation on remedies would not apply if (1) it would materially and adversely affect a legitimate contract-based expectation in existence before January 1, 2004, or (2) the party seeking remedies was a bona fide purchaser of the patent and, at the time of purchase, did not know that the State had formerly been the owner of the patent. The legislation was intended to legislatively overrule the U.S. Supreme Court’s decision in *Florida Prepaid Postsecondary Education Expense Board v. College Savings Bank*, which ruled that states could not be sued for patent infringement because they had not waived their Eleventh Amendment immunity from suit.<sup>19</sup>

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<sup>15</sup> *Id.*

<sup>16</sup> Consolidated Appropriations Act of 2004, Pub. L. No. 108-199, 118 Stat. 3 (2004).

<sup>17</sup> Intellectual Property Protection Restoration Act of 2003, S. 1191, 108th Cong. (2003); H.R. 2344, 108th Cong. (2003).

<sup>18</sup> *Id.*

<sup>19</sup> 527 U.S. 627, 645 (1999).

*D. (Proposed) Cooperative Research and Technology Enhancement Act of 2003*

This proposed bill<sup>20</sup> was introduced to overrule the Federal Circuit's decision in *OddzOn Products, Inc. v. Just Toys, Inc.*<sup>21</sup> In that case, the Federal Circuit ruled that activities under 35 U.S.C. § 102(f) (derivation of the invention) could be used under the statute to invalidate a patent on grounds of obviousness.<sup>22</sup> In other words, allegedly collaborative projects between two companies could create unintended prior art because the work of one company could be treated as "prior art" under § 102(f) as to the inventive entity named on the patent.<sup>23</sup> Various universities testified in favor of overturning this ruling.

The bill would have amended § 102(f) to exclude activities under that section from being used as prior art in determining obviousness under § 103. In response to various objections, the bill was amended to instead change § 103(c) to provide that (1) subject matter and inventions owned by parties to a joint research agreement would be deemed owned by the same person, thereby falling within the § 103(c) exclusion, and (2) the time for determining applicability of this exclusion would be the applicable patent filing date rather than the date of invention.<sup>24</sup> The bill has been received in the Senate and referred to the Committee on the Judiciary.<sup>25</sup>

*E. (Proposed) Jobs Growth and Tax Act of 2003*

This bill would amend 26 U.S.C. § 170 (I.R.S. code), to limit charitable deductions of intellectual property, including patents.<sup>26</sup> Currently, deductions are permitted for charitable contributions, with the amount of the deduction equal to the fair market value of the contributed property on the date of the contribution.<sup>27</sup> Criticism has arisen over the past year stemming from questionable valuations of patents donated to charitable organizations, such as universities. If enacted, this provision would limit the tax savings realized by taxpayers (including corporations) when donating patents to non-profit institutions.

*F. (Proposed) U.S. Patent and Trademark Fee Modernization Act of 2003*

This bill<sup>28</sup> would change the patent fee structure (for large entities), as follows:

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<sup>20</sup> Cooperative Research and Technology Enhancement (Create) Act of 2003, H.R. 2391, 108th Cong. (2003).

<sup>21</sup> 122 F.3d 1396 (Fed. Cir. 1997).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> Cooperative Research and Technology Enhancement (Create) Act of 2003, H.R. 2391, 108th Cong. (2003).

<sup>25</sup> The current status of bill H.R. 2391 is available on the Thomas Legislative Information website at <http://thomas.loc.gov>.

<sup>26</sup> Jobs and Growth Tax Act of 2003, S. 2, 108th Cong. § 364 (2003); Jump Start Our Business Strength (Jobs) Act, S. 1637, 108th Cong. § 495 (2003).

<sup>27</sup> 26 U.S.C. § 170 (2003).

<sup>28</sup> Patent and Trademark Fee Modernization Act of 2003, H.R. 1561, 108th Cong. (2003); Patent and Trademark Fee Modernization Act of 2003, S. 1760, 108th Cong. (2003).

- Application fees for utility patents would be reduced from \$750 to \$300.
- The fee for each independent claim in excess of 3 would increase from \$84 to \$200; the fee for each claim in excess of 20 would increase from \$18 to \$50; and the fee for an application containing a multiple dependent claim would increase from \$160 to \$360.
- Additional fees would be charged if the application is examined; the examination fee would be \$200 for a utility application, \$130 for a design application, \$160 for a plant patent application, \$200 for the national stage of an international application, and \$600 for a reissue application.
- Issue fees would increase from \$1,300 to \$1,400 for a utility or reissue patent, from \$470 to \$800 for a design patent, and from \$630 to \$1,100 for a plant patent.
- Appeal fees would increase from \$320 to \$500 for filing the appeal, \$320 to \$500 for filing an appeal brief, and \$280 to \$1,000 for requesting an oral argument.
- Time-extension fees would increase from \$110 to \$120 for the first month, \$300 to \$330 for the second month, and \$520 to \$570 for the third month.
- Maintenance fees would increase from \$890 to \$900 at 3 ½ years, from \$2,050 to \$2,300 at 7 ½ years, and from \$3,150 to \$3,800 at 11 ½ years.

## II. PTO REGULATORY DEVELOPMENTS

### *A. Revision of Patent Cooperation Treaty (PCT) Application Procedures*

The United States Patent and Trademark Office (“PTO”) adopted final rules relating to Patent Cooperation Treaty (“PCT”) applications, effective January 1, 2004.<sup>29</sup> Among other things, the amendments improve coordination of the international search (Chapter I of the PCT) and international preliminary examination (Chapter II of the PCT), and simplify the designation of countries, fees, signatures and other filing requirements.<sup>30</sup>

The changes add to the Chapter I procedure the written opinion prepared during the Chapter II procedure by the International Preliminary Examining Authority (IPEA).<sup>31</sup> The International Searching Authority (ISA) will be responsible for preparing a preliminary and non-binding written opinion on whether the claimed invention is novel, includes an inventive step, and has industrial applicability. If a Demand for international preliminary examination is timely filed, the ISA’s written opinion will be deemed to be the IPEA’s written opinion. If, however, a Demand is not timely filed, the ISA’s written opinion will form the basis for issuance by the International Bureau on behalf of the ISA of an International Preliminary Report on Patentability, which will be sent to all designated Offices and made available for public inspection 30 months from the priority date.

The time limit for filing a Demand for international preliminary inspection has been changed. Now, the Demand must be filed by the later of (1) three months from issuance

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<sup>29</sup> January 2004 Revision of Patent Cooperation Treaty Application Procedure, 68 Fed. Reg. 67805 (Dec. 4, 2003) (codified at 37 C.F.R. pt. 1).

<sup>30</sup> The changes are contained in 37 C.F.R. §§ 1.14(g)(1)(ii) and g(3), 1.413, 1.421, 1.431, 1.432, 1.434, 1.445, 1.455, 1.480, 1.481, 1.482 and 1.484. 37 C.F.R. §§ 1.424 and 1.425 have been deleted.

<sup>31</sup> 37 C.F.R. § 1.484 (2004).

of the international search report and the ISA's written opinion (or, if a search cannot be made, of the Article 17.2(a) declaration), or (2) 22 months from the priority date. Any arguments or amendments in response to the ISA's opinion must be submitted within the time limit for filing the Demand to ensure consideration by the IPEA.

Payment of the international preliminary examination fee and handling fee is not required until the later of one month from the filing of the Demand or 22 months from the priority date.<sup>32</sup> If the IPEA and ISA are the same, and the IPEA wants to start examination at the same time as the international search, the IPEA may require payment of the examination and handling fee within one month of invitation for payment by the IPEA.<sup>33</sup>

Upon filing a PCT application, the applicant will obtain automatic coverage for all designation countries available under the PCT, including national and regional patent protection.<sup>34</sup> Similarly, the mere filing of a Demand will constitute the election of all designated states.<sup>35</sup> Applicants no longer need to designate individual countries at the time of filing. The automatic designation provisions avoid problems for applicants who neglect to designate at the time of filing the PCT application.

The fee system has been changed to a single international filing fee (including a first fee component for up to 30 sheets and a second fee component for pages over 30). This eliminates the requirement of a "basic fee" and a "designation fee," each of which was due at different times in different amounts, depending on when they were paid.

Because of the automatic designation system, applicants/inventors must be named in the PCT application. To avoid problems in obtaining signatures of all applicants, PCT Rule 26 has been amended to provide that, for purposes of Article 14(a)(i), the PCT application will be considered as signed if the request is signed by at least one applicant.<sup>36</sup> If the PTO is the Receiving Office, this information must be provided for at least one applicant who is a citizen or resident of the United States. The designated/elected Office may, during the national stage, still require confirmation of the PCT application by the signature of any applicant who has not signed the Request and any missing identifying information.<sup>37</sup>

PCT Rule 90.4 has been revised to permit the Receiving Office, ISA or IPEA to waive the requirement for a power of attorney, except where the applicant initiates withdrawals under PCT Rule 90*bis*.<sup>38</sup>

### *B. Elimination of CPA Practice for Utility and Plant Patent Applications*

The American Inventors Protection Act of 1999 provided for continued examination ("CPA") of a utility or plant patent application at the applicant's request (request for continued examination or RCE). Since continued prosecution applications are largely redundant in view of RCEs, the PTO enacted a rule eliminating CPA's. This amendment

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<sup>32</sup> Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, Rules 57.3(a) and 58.1(b), *available at* [http://www.wipo.int/pct/en/texts/pdf/pct\\_regs.pdf](http://www.wipo.int/pct/en/texts/pdf/pct_regs.pdf) (last visited April 9, 2004).

<sup>33</sup> *Id.* at Rule 57.3(c).

<sup>34</sup> *Id.* at Rule 4.9.

<sup>35</sup> *Id.* at Rule 53.7.

<sup>36</sup> *Id.* at Rule 26.2*bis* (a).

<sup>37</sup> *Id.* at Rule 51*bis* 1(a).

<sup>38</sup> *Id.* at Rule 90.4.

became effective July 14, 2003. It amends 37 C.F.R. § 1.53(d)(1) to provide that CPA's may be filed only for design patent applications. If an improper request is made for a CPA, it will be treated as an RCE.

### *C. Electronic Maintenance of Official Patent Application Records*

Effective July 30, 2003, the PTO adopted rules as part of its 21<sup>st</sup> Century Strategic Plan to implement beginning-to-end electronic image processing of patent applications. The changes facilitate electronic image data capture and processing, streamline the patent application process, and simplify and clarify the pertinent rules of practice.<sup>39</sup>

The new system, referred to as the Image File Wrapper ("IFW") system, uses digital image technology to replace paper processing of patent applications. The papers for patent applications will be scanned into electronic files, and all processing and examination by the PTO will be conducted with the electronic files. Because application files will be stored in electronic format, they can be viewed by the public through the PAIR system.

### *D. Proposed Rule Changes to Implement the PTO's 21st Century Strategic Plan*

The PTO published proposed rules to implement the 21st Century Strategic Plan.<sup>40</sup> Among other things, the changes allow electronic signatures on various submissions, streamline the requirement for incorporation by reference of prior-filed applications, and clarify the requirements for claiming small entity status.

### *E. Proposed Rule Changes for Practice Before the PTO Board of Appeals*

The PTO published proposed rule changes relating to practice before the Board of Patent Appeals and Interferences.<sup>41</sup> A new Part 41 of the Rules would be adopted for the purpose of consolidating and simplifying the rules relating to Board practice. The purpose of these amendments is to improve procedures governing Board proceedings and to reflect case law and legislative changes since the last significant changes.

### *F. Proposed Rule Changes for Representation of Others Before the PTO*

The PTO has proposed sweeping changes governing the right of patent agents and attorneys to represent others before the PTO. Among other things, the proposed rules would: 1) add new fees to fund periodic examination of registered attorneys and agents on a continuing basis, 2) establish a continuing education program for all registered

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<sup>39</sup> Changes to Implement Electronic Maintenance of Official Patent Application Records, 68 Fed. Reg. 38611 (June 30, 2003) (codified at 37 C.F.R. pt. 1).

<sup>40</sup> Changes To Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan, 68 Fed. Reg. 53816 (Sept. 12, 2003) (to be codified at 37 C.F.R. pt. 1).

<sup>41</sup> Rules of Practice Before the Board of Patent Appeals and Interferences, 68 Fed. Reg. 66648 (Nov. 26, 2003) (to be codified at 37 C.F.R. pts. 1, 5 and 41).



practitioners, 3) permit the PTO to examine financial records of a practitioner, and 4) expand the right of the PTO to conduct disciplinary investigations.<sup>42</sup>

### III. CASE LAW DEVELOPMENTS

#### A. Patentability, Validity, and Procurement

##### 1. Written Description

In *Moba, B.V. v. Diamond Automation, Inc.*, a claim that recited a step of lifting eggs from a moving conveyor belt was adequately supported by the written description, which showed that the inventor was in possession of that limitation as of the filing date.<sup>43</sup> In a concurring opinion, Judge Rader criticized the use of the written description requirement to police anything other than priority issues.<sup>44</sup>

##### 2. On-Sale Bar

In *Lacks Industries, Inc. v. McKechnie Vehicle Components USA, Inc.*, the Federal Circuit vacated and remanded a ruling that the patented invention was on sale more than one year before the filing date, because the district court applied the wrong standard for determining whether there was a commercial offer for sale.<sup>45</sup> Applying its 2001 decision in *Group One*,<sup>46</sup> which looked to the Uniform Commercial Code to determine whether an offer was legally binding, the Federal Circuit stated that the court should look at industry custom and practice to determine whether Lacks's solicitations rose to the level of a commercially binding offer for sale.<sup>47</sup> In her dissenting opinion, Judge Newman criticized the deviation from a uniform standard for determining whether an offer constitutes an invalidating offer for sale, stating that "remand for the purpose of ascertaining that industry practice is at variance with *Pfaff* and its implementing precedent."<sup>48</sup>

In *Minton v. National Association of Securities Dealers, Inc.*, a patent for a computerized securities trading method was held to be invalid because more than one

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<sup>42</sup> Changes to Representation of Others Before the United States Patent and Trademark Office, 68 Fed. Reg. 69442 (Dec. 12, 2003) (to be codified at 37 C.F.R. pts 1, 2, 10 and 11).

<sup>43</sup> 325 F.3d 1306, 1319 (Fed. Cir. 2003).

<sup>44</sup> *Id.* at 1322 (Rader, J., concurring).

<sup>45</sup> 322 F.3d 1335, 1351 (Fed. Cir. 2003)

<sup>46</sup> *Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041 (Fed. Cir. 2001). "[O]nly an offer which rises to the level of a commercial offer for sale, one which the other party could make into a binding contract by simple acceptance (assuming consideration), constitutes an offer for sale under § 102(b)." *Id.* at 1048.

<sup>47</sup> *Lacks*, 322 F.3d at 1347.

year before the filing date, Minton leased a computer program that carried out the patented process.<sup>49</sup> The court distinguished its earlier *In re Kollar*<sup>50</sup> decision on the basis that *Kollar* involved a mere transfer of technical information for a process that required further development.<sup>51</sup>

### 3. Enablement

In *Plant Genetic Systems, N.V. v. DeKalb Genetics Corp.*, the Federal Circuit held that “pioneer” patents are not entitled to a lower standard of enablement than other patents.<sup>52</sup> The Court upheld the district court’s determination that the claimed invention was invalid because the patent did not enable a person of ordinary skill in the art to make the invention as claimed.<sup>53</sup>

### 4. Anticipation

In *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, a patent for an antihistamine metabolite was anticipated by a prior patent for the underlying antihistamine.<sup>54</sup> Schering’s prior ‘223 patent covers the compound used in its CLARITIN® antihistamine.<sup>55</sup> Its later ‘716 patent covers a metabolite of the compound which differs slightly from the compound shown in the original ‘223 patent.<sup>56</sup> According to the Federal Circuit, even though the metabolite was not specifically shown in the earlier ‘223 patent, it was inherently disclosed in the patent because ingestion of the drug described in the ‘223 patent would necessarily result in the creation of the metabolite claimed in the later ‘716 patent.<sup>57</sup> Three judges dissented from the denial of an en banc rehearing.<sup>58</sup>

### 5. Obviousness

In *In re Peterson*, the Federal Circuit upheld the PTO’s determination that Peterson’s claimed invention, which recited a range of 1% to 3% rhenium and about 14% chromium, was obvious over a prior art reference that showed a range of 0% to 7%

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<sup>48</sup> *Id.* at 1352 (Newman, J., dissenting); see generally *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 67 (1998).

<sup>49</sup> 336 F.3d 1373, 1381 (Fed. Cir. 2003).

<sup>50</sup> 286 F.3d 1326 (Fed. Cir. 2002).

<sup>51</sup> *Minton*, 336 F.3d at 1377.

<sup>52</sup> 315 F.3d 1335, 1339 (Fed. Cir. 2003).

<sup>53</sup> *Id.* at 1340.

<sup>54</sup> 339 F.3d 1373, 1375 (Fed. Cir. 2003) (a metabolite is a compound formed in the patient’s body upon ingestion of a pharmaceutical), *en banc reh’g denied*, 348 F.3d 992 (Fed. Cir. 2003).

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* at 1381.

<sup>58</sup> *Schering Corp. v. Geneva Pharm., Inc.*, 348 F.3d 992, 993 (Fed. Cir. 2003). Judge Newman dissented from the denial of rehearing en banc, Judge Lourie dissented from the denial of the petition for rehearing en banc, and Judge Gajarsa would rehear the appeals en banc. *Id.*

renium and 3% to 18% chromium.<sup>59</sup> According to the Federal Circuit, “[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”<sup>60</sup> The inventor did not show any unexpected increase in strength in the claimed range of 1% to 3%.<sup>61</sup>

#### 6. Admissions As Prior Art

In *Riverwood International Corp. v. R.A. Jones & Co.*, the fact that a patent was listed on an Information Disclosure Statement did not constitute an admission that the earlier patent was prior art.<sup>62</sup> The Federal Circuit distinguished the CCPA’s decision in *In re Nomiya*<sup>63</sup> as being limited to admissions concerning “prior art” invented by others (i.e., not the inventor).<sup>64</sup> In this case, one of the inventors on the patent at issue was an inventor on the earlier patent, which did not in fact constitute prior art.<sup>65</sup> The Federal Circuit stated that “[w]hile *Nomiya* and *Fout* stand for the proposition that a reference can become prior art by admission, that doctrine is inapplicable when the subject matter at issue is the inventor’s own work.”<sup>66</sup>

#### 7. Indefiniteness

In *Honeywell International, Inc. v. International Trade Commission*, a claim was held invalid for indefiniteness where the recited limitation of a “melting point elevation” reaching a certain point could not be measured without knowing which of four different known sample preparation methods was to be used, and the patent did not identify what method should be used.<sup>67</sup> Depending on which method was used, a different number would be obtained.<sup>68</sup>

#### 8. Double Patenting

In *Geneva Pharmaceuticals, Inc. v. Glaxosmithkline PLC*, several Glaxo patents covering an antibiotic drug were held invalid for double patenting, even though the PTO had allegedly issued a restriction requirement in an earlier application.<sup>69</sup> The Federal Circuit held that an ambiguous examiner interview summary stating that “method of use claims will go in a divisional application” did not constitute a clear restriction

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<sup>59</sup> 315 F.3d 1325, 1327 (Fed. Cir. 2003).

<sup>60</sup> *Id.* at 1331.

<sup>61</sup> *Id.* at 1332.

<sup>62</sup> 324 F.3d 1346, 1355 (Fed. Cir. 2003).

<sup>63</sup> 509 F.2d 566 (C.C.P.A. 1975).

<sup>64</sup> *Riverwood*, 324 F.3d at 1354.

<sup>65</sup> *Id.* at 1355.

<sup>66</sup> *Id.* at 1354; see generally *In re Fout*, 675 F.2d 297 (C.C.P.A. 1982)

<sup>67</sup> 341 F.3d 1332, 1339 (Fed. Cir. 2003)

<sup>68</sup> *Id.* at 1336.

requirement.<sup>70</sup> According to the court, “restriction requirements must provide a clear demarcation between restricted subject matter to allow determination that claims in continuing applications are consonant and therefore deserving of § 121’s protections.”<sup>71</sup>

## B. Interpretation of Patents

### 1. Claim Construction

In *Invitrogen Corp. v. Biocrest Manufacturing, L.P.*, a claim that recites a first step of growing cells at a temperature of 18° C to 32° C was improperly interpreted to preclude an additional step (prior to the first step) of growing cells at 37° C (i.e., foreclosing any growth outside of the claimed range).<sup>72</sup> During prosecution, the patent examiner had stated that the 18° C to 32° C range was essential to the invention.<sup>73</sup> In response, the applicants amended the claim to recite that range and argued that the claimed range avoided undesirable effects of growth at 37° C.<sup>74</sup> According to the Federal Circuit, this did not preclude the applicant from asserting the claims against an accused method that first applied growth at 37° C and then followed the claimed steps.<sup>75</sup>

In *Northrop Grumman Corp. v. Intel Corp.*, a district court erred by interpreting the claimed term “bus interface unit” as being limited to a unit capable of functioning in a command/response system.<sup>76</sup> Despite the fact that the specification highlighted the command/response system in various objects of the invention, the Federal Circuit adopted the ordinary meaning of the term, continuing its trend toward giving a “heavy presumption” to the ordinary meaning of claim language.<sup>77</sup> The court also stated that components that were not necessary to perform a recited function of a means-plus-function clause cannot qualify as “corresponding” structure under 35 U.S.C. § 112, ¶ 6.<sup>78</sup>

In *Kumar v. Ovonic Battery Co.*, although dictionaries can be an important tool in claim construction by providing a starting point for determining the ordinary meaning of a term, the Federal Circuit relied instead on a definition of the word “amorphous” that was found in a prior art patent that was discussed during prosecution of the patent at issue.<sup>79</sup> The defendant had argued that the ordinary dictionary definition of “amorphous” should be used.<sup>80</sup> The Federal Circuit noted that the prior art patent was considered part of the intrinsic record and contained a definition that was “to be

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<sup>69</sup> 349 F.3d 1373, 1376 (Fed. Cir. 2003) (stating that 35 U.S.C. § 121 precludes use of one patent against another if they resulted from a restriction requirement in the USPTO).

<sup>70</sup> *Id.* at 1380.

<sup>71</sup> *Id.* at 1381.

<sup>72</sup> 327 F.3d 1364, 1368 (Fed. Cir. 2003).

<sup>73</sup> *Id.* at 1369.

<sup>74</sup> *Id.* at 1370.

<sup>75</sup> *Id.*

<sup>76</sup> 325 F.3d 1346, 1356 (Fed. Cir. 2003).

<sup>77</sup> *Id.* at 1355.

<sup>78</sup> *Id.* at 1350.

<sup>79</sup> 351 F.3d 1364, 1366 (Fed. Cir. 2003).

<sup>80</sup> *Id.* at 1367.

preferred” over the general dictionary definition.<sup>81</sup> The patent specification did not specifically define the term.<sup>82</sup>

In *Genzyme Corp. v. Transkaryotic Therapies, Inc.*, the applicant made an allegedly broadening amendment to the claims after a final rejection, but did not provide any explanation for the amendment, and the Federal Circuit concluded that it could not have been a broadening amendment.<sup>83</sup> The Federal Circuit pointed to PTO Rule 1.116, which does not permit entry of amendments “touching the merits of the application” after a final rejection unless the applicant makes a showing of good and sufficient reasons why they are necessary and were not earlier presented.<sup>84</sup> According to the Federal Circuit, the examiner could not accept a second (supplemental) after-final amendment broadening the scope of the rejected claims without formal comment from the applicant. Under the applicable Patent Office Rules, amendments to patent claims after final rejection cannot alter the substantive scope of the claims without explanation about the necessity of the amendment and without reasons for the delay in proposing the change.<sup>85</sup>

The court interpreted the phrase “chromosomally integrated” to require introduction of exogenous -Gal A sequences into a host cell, and hence the patent was not infringed.<sup>86</sup>

In *Altiris, Inc. v. Symantec Corp.*, a method claim was held not to be limited to the specific ordering of steps as recited in the claim.<sup>87</sup> The Federal Circuit vacated the district court’s conclusion that the specification implicitly required such an ordering.<sup>88</sup> On a second issue, the Federal Circuit ruled that despite the fact that the recited term “boot selection flag” did not have a common meaning in the art, a proper meaning could be determined by looking at the individual meanings of “boot,” “selection,” and “flag.”<sup>89</sup> The Federal Circuit looked to dictionary definitions for these words and concluded that “boot selection flag” referred to one or more bits of data or information indicating which boot cycle had been selected.<sup>90</sup> As to another phrase, however, (“automation code”), the Federal Circuit concluded that dictionary definitions of the words did not give any clarity to the claim term, so resort to the specification was necessary to determine its meaning.<sup>91</sup>

In *Jansen v. Rexall Sundown, Inc.*, a claimed method for treating pernicious anemia by administering folic acid and vitamin B12 “to a human in need thereof” was properly limited to uses for patients who knew they were in need of treatment of pernicious anemia.<sup>92</sup> The defendant marketed a product that fell within the language of the claim except that it was marketed for maintenance of proper blood homocysteine levels, not for

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<sup>81</sup> *Id.* at 1368.

<sup>82</sup> *Id.* at 1369.

<sup>83</sup> 346 F.3d 1094, 1111 (Fed. Cir. 2003).

<sup>84</sup> *Id.* at 1103.

<sup>85</sup> *Id.*

<sup>86</sup> *Id.* at 1101, 1106.

<sup>87</sup> 318 F.3d 1363, 1371 (Fed. Cir. 2003).

<sup>88</sup> *Id.* at 1372.

<sup>89</sup> *Id.* at 1366. “Simply because a phrase as a whole lacks a common meaning does not compel a court to abandon its quest for a common meaning and disregard the established meanings of the individual words.” *Id.* at 1372.

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

<sup>91</sup> *Id.* at 1374.

<sup>92</sup> 342 F.3d 1329, 1330 (Fed. Cir. 2003).

treatment of anemia.<sup>93</sup> The Federal Circuit rejected the patent owner's argument that all persons were "humans in need" of such treatment.<sup>94</sup>

In *Alloc, Inc. v. International Trade Commission*, claims that did not explicitly recite "play" (space) between panels were nevertheless interpreted to require such "play," because the specification and prosecution history emphasized such "play."<sup>95</sup> Judge Schall wrote a lengthy dissent emphasizing the lack of anything in the claims implying "play."<sup>96</sup>

### 2. Doctrine of Equivalents (Scope of Claims)

In *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, on remand from the Supreme Court in light of *Festo*, the Federal Circuit again concluded that Space Systems/Loral did not infringe the patent, but this time it applied the "all elements" rule.<sup>97</sup> In its original decision, the Federal Circuit held that the patent was not infringed under the doctrine of equivalents because of prosecution history estoppel.<sup>98</sup> After the Supreme Court vacated and remanded in light of its ruling in *Festo*, the Federal Circuit found a different reason to find the patent not infringed, invoking the "all elements" rule.<sup>99</sup> According to the Federal Circuit, the district court erred by identifying the claimed limitation as "rotating said wheel," rather than "rotating said wheel in accordance with a predetermined rate schedule which varies sinusoidally over the orbit at the orbital frequency of the satellite."<sup>100</sup> Given that this more specific limitation was missing from the accused device, no infringement could be found.<sup>101</sup>

In *Abbott Laboratories v. Novopharm Ltd.*, the "all elements rule" was invoked to preclude infringement under the doctrine of equivalents.<sup>102</sup> The claim recited "a comicronized mixture of particles of fenofibrate and a solid surfactant."<sup>103</sup> The defendant used a non-solid surfactant, and the court thus held that asserting equivalents infringement would "vitiating that limitation altogether."<sup>104</sup>

### 3. Prosecution History Estoppel

In *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, Pioneer was estopped from asserting that its patent was infringed under the doctrine of equivalents.<sup>105</sup> The Federal

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> 342 F.3d 1361, 1367 (Fed. Cir. 2003), *en banc reh'g denied*, 2003 U.S. App. LEXIS 25565 (Fed. Cir. Nov. 17, 2003).

<sup>96</sup> *Id.* at 1375 (Schall, J., dissenting).

<sup>97</sup> 324 F.3d 1308, 1309, 1321 (Fed. Cir. 2003).

<sup>98</sup> *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 249 F.3d 1314, 1327 (Fed. Cir. 2001), *en banc reh'g denied*, 2001 U.S. App. LEXIS 16600 (Fed. Cir. June 25, 2001), *vacated and remanded*, 535 U.S. 1109 (2002), *recalled and appeal reinstated*, 2002 U.S. App. LEXIS 15608 (2002).

<sup>99</sup> *Lockheed*, 324 F.3d at 1321.

<sup>100</sup> *Id.* at 1315.

<sup>101</sup> *Id.* at 1321.

<sup>102</sup> 323 F.3d 1324, 1328 (Fed. Cir. 2003).

<sup>103</sup> *Id.* at 1327.

<sup>104</sup> *Id.* at 1331. This case illustrates how a "limitation" can be as narrow as a single word.

<sup>105</sup> 330 F.3d 1352, 1354 (Fed. Cir. 2003).

Circuit held that Pioneer could not rely on a declaration by the patent attorney to explain that the narrowing amendment was “inadvertent.”<sup>106</sup> The Court stated that “only the public record of the patent prosecution, the prosecution history, can be a basis for such a reason [for the amendment].”<sup>107</sup> The Court also rejected the argument that because the amendment was voluntary, it did not give rise to estoppel.<sup>108</sup> Finally, the court ruled that Pioneer could not overcome the presumption that it had surrendered the alleged equivalent, because the equivalent was well known at the time of the amendment.<sup>109</sup>

In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, in this long-awaited decision on remand from the Supreme Court, the en banc Federal Circuit clarified the nature of prosecution history estoppel.<sup>110</sup> The Supreme Court had previously ruled that amending a patent claim during prosecution did not necessarily create a complete bar for purposes of infringement under the doctrine of equivalents, although making a narrowing amendment without any explanation would give rise to a rebuttable presumption that the equivalent in question had been surrendered.<sup>111</sup> The Supreme Court had identified three circumstances in which the presumption could be rebutted: (1) where the accused equivalent was not foreseeable at the time of the amendment; (2) where the amendment bore no more than a “tangential” relation to the accused equivalent; or (3) where “some other reason” prevented the patent owner from covering the accused equivalent in the claims.<sup>112</sup> The Federal Circuit further developed the Supreme Court’s ruling, stating:

(1) whether the presumption of surrender had been rebutted was a purely legal issue, despite potential fact issues regarding the level of skill in the art;

(2) specific factors to be considered in evaluating the rebuttal would be developed on a case-by-case basis;

(3) unforeseeability is an objective inquiry relating to what a person of ordinary skill in the art would have foreseen at the time the amendment was made;

(4) later-developed technology is generally not foreseeable for purposes of rebuttal;

(5) earlier-developed technology is likely to have been foreseeable; and

(6) a district court may hear expert testimony and consider extrinsic evidence regarding whether an alleged equivalent would have been foreseeable, but “tangential relation” and “some other reason” reasons should be determined based solely on the prosecution history.<sup>113</sup>

Additionally, the “tangential relation” reason could not be relied upon if the alleged equivalent was present in the prior art that the amendment was intended to overcome. The court remanded in this case to determine whether one of ordinary skill would have thought that a single two-way sealing ring was an objectively unforeseeable equivalent of two one-way sealing rings.<sup>114</sup>

In *Ranbaxy Pharmaceuticals, Inc. v. Apotex, Inc.*, rewriting a dependent claim in independent form in response to an examiner’s objection was held to constitute a

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<sup>106</sup> *Id.* at 1357.

<sup>107</sup> *Id.*

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

<sup>109</sup> *Id.*

<sup>110</sup> 344 F.3d 1359, 1363 (Fed. Cir. 2003).

<sup>111</sup> *Id.* at 1365.

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

<sup>113</sup> *Id.* at 1367–70.

<sup>114</sup> *Id.* at 1371.

narrowing amendment for purposes of prosecution history estoppel, and there was a rebuttable presumption that the alleged equivalent was surrendered.<sup>115</sup> The Federal Circuit concluded based on the evidence before it that the alleged equivalent (acetic acid) was likely foreseeable at the time of the amendment, and the patent owner surrendered coverage for the equivalent.<sup>116</sup>

In *Talbert Fuel Systems Patents Co. v. Unocal Corp.*, in one of the first decisions issued after its revised *Festo* decision was released, the Federal Circuit held that amending a claim to recite “a boiling point range of 121F to 345F” in the face of a prior art rejection that showed a boiling point of 390F constituted a narrowing amendment that surrendered coverage over an alleged equivalent that fell within the surrendered range of 345F to 390F.<sup>117</sup> The court refused to remand to permit Talbert to introduce new evidence in an attempt to overcome the rebuttal, concluding that the *Festo* rebuttal criteria could not be met.<sup>118</sup>

In *Deering Precision Instruments, LLC v. Vector Distribution Systems, Inc.*, although Deering narrowed its claims by canceling broader claims and substituting narrower claims, the Federal Circuit remanded to determine whether Deering could rebut the *Festo* presumption that the alleged equivalents had been surrendered.<sup>119</sup> The court did not explain what evidence might be relied upon to rebut the presumption.<sup>120</sup>

### C. Enforcement of Patents

#### 1. Ownership

In *Regents of the University of New Mexico v. Knight*, university faculty members were held to have been contractually obligated to assign to the university their rights in patents and patent applications, based on the university’s patent policy and by conduct indicating that the professors intended to be bound by the patent policy.<sup>121</sup> Two faculty members assigned several patent applications to the University of New Mexico arising from their work at the university.<sup>122</sup> However, they refused to assign several continuation-in-part applications to the university.<sup>123</sup> The university brought suit seeking a declaration of ownership based on breach of the university’s Intellectual Property Policy and a Co-Inventor Agreement.<sup>124</sup> The Federal Circuit concluded that one of the faculty members had entered into a written contract that incorporated the university’s patent policy, and that the other faculty member was bound under the policy

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<sup>115</sup> 350 F.3d 1235, 1240 (Fed. Cir. 2003).

<sup>116</sup> *Id.* at 1241. The appeal was from the denial of a preliminary injunction, so presumably additional evidence could be introduced during further proceedings in the district court.

<sup>117</sup> 347 F.3d 1355, 1357–1360 (Fed. Cir. 2003).

<sup>118</sup> *Id.* at 1360.

<sup>119</sup> 347 F.3d 1314, 1327 (Fed. Cir. 2003).

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

<sup>121</sup> 321 F.3d 1111, 1116 (Fed. Cir. 2003).

<sup>122</sup> *Id.* at 1114.

<sup>123</sup> *Id.* at 1115.

<sup>124</sup> *Id.* at 1114.



because, under New Mexico law, a written personnel policy may form an implied employment contract.<sup>125</sup>

## 2. Infringement Issues

In *Integra Lifesciences I, Ltd. v. Merck KGaA*, Merck had conducted research using patented peptides to identify new drugs.<sup>126</sup> Integra sued Merck, claiming its use constituted patent infringement.<sup>127</sup> Merck defended that its use of the patented peptides was exempt from infringement under 35 U.S.C. § 271(e)(1), which was intended to permit generic drug companies to begin testing drugs to enter the market after patent expiration. Relying in part on legislative history, the Federal Circuit held that Merck's activities did not fall within the § 271 exemption.<sup>128</sup> Because Merck's research was not directly related to submitting information to the FDA concerning a particular drug, but was instead directed to identifying new drugs, the exemption did not apply.<sup>129</sup> Judge Newman dissented, arguing for a common law research exemption from infringement.<sup>130</sup>

In *Bayer AG v. Housey Pharmaceuticals, Inc.*, information generated overseas using a patented process and then "imported" into the United States was held not to constitute a "product" for purposes of infringement under 35 U.S.C. § 271(g).<sup>131</sup> Housey claimed that Bayer used Housey's patented method to identify a pharmacologically active agent and then "imported" that information into the United States.<sup>132</sup> The Federal Circuit concluded that § 271(g) was limited to manufactured physical goods, thus excluding intangible information.<sup>133</sup>

## 3. Implied License

In *Anton/Bauer, Inc. v. PAG, Ltd.*, a patent owner who sold female connectors intended to be mated with male connectors necessarily granted an implied license to its customers to practice the claimed invention, which required both male and female connectors.<sup>134</sup> Anton/Bauer's patent claims recited both a "flat male plate" and a "flat female plate."<sup>135</sup> Anton/Bauer makes and sells both female plates and battery packs containing male plates.<sup>136</sup> Instead of selling the combination, however, it sells female plates to video camera manufacturers, and sells the male plates separately.<sup>137</sup> The defendant sold battery packs containing only a male plate that can be used with

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<sup>125</sup> *Id.* at 1128.

<sup>126</sup> 331 F.3d 860, 863 (Fed. Cir. 2003).

<sup>127</sup> *Id.*

<sup>128</sup> *Id.* at 868.

<sup>129</sup> *Id.* at 867.

<sup>130</sup> *Id.* at 872 (Newman, J., dissenting).

<sup>131</sup> 340 F.3d 1367, 1368 (Fed. Cir. 2003).

<sup>132</sup> *Id.* at 1369.

<sup>133</sup> *Id.* at 1368.

<sup>134</sup> 329 F.3d 1343, 1347 (Fed. Cir. 2003).

<sup>135</sup> *Id.* at 1346.

<sup>136</sup> *Id.* at 1347.

<sup>137</sup> *Id.*

Anton/Bauer's female plates.<sup>138</sup> The Federal Circuit held that Anton/Bauer could not proceed under an induced infringement or contributory infringement theory, because its customers had an implied license to use the patented combination, and without any direct infringement there could be no contributory or induced infringement by PAG.<sup>139</sup>

#### 4. Damages

In *Integra Lifesciences I, Ltd. v. Merck KGaA*, a jury award of \$15 million in reasonable royalty damages was vacated and remanded.<sup>140</sup> The Federal Circuit found that the damages analysis was flawed because (1) reliance on a previous license entered into by Merck with another company was improper because it did not involve an analogous level of risk; and (2) the amount of damages was nearly the entire value of a company that Integra had purchased, which included many other patents.<sup>141</sup>

#### 5. Unenforceability Due To Prosecution Laches

In the closely watched case of *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation*, bar code manufacturers representing more than 90% of the bar code reader industry sued the Lemelson Foundation to stop it from suing hundreds of companies over patents that claim priority back to the 1950s.<sup>142</sup> One major defense raised by the bar code manufacturers is that Lemelson's patents are unenforceable because of "prosecution laches"—in other words, undue and unexplained delays at the patent office.<sup>143</sup>

On January 23, 2004, the district court ruled against Lemelson, concluding that all of his patents were unenforceable due to "prosecution laches."<sup>144</sup> In particular, the court noted that Lemelson's 18 to 39-year delay in filing the asserted claims after they were first disclosed in 1954 and 1956 was unexplained and unreasonable.<sup>145</sup> The court found that Lemelson held the U.S. record for longest pendency of patent applications.<sup>146</sup> An appeal is expected.

The "prosecution laches" defense was first explicitly recognized by the Federal Circuit a year ago in *Symbol Technologies, Inc. v. Lemelson Medical, Education & Research Foundation*.<sup>147</sup> The equitable doctrine of laches can bar enforcement of a patent that issued after an unreasonable and unexplained delay in prosecution, even though the patent applicant complied with the patent statute and rules.<sup>148</sup> The Federal Circuit concluded that enactment of §§ 120 and 121 of the patent statute, which

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<sup>138</sup> *Id.*

<sup>139</sup> *Id.* at 1345, 1353.

<sup>140</sup> 331 F.3d 860, 862 (Fed. Cir. 2003).

<sup>141</sup> *Id.* at 872.

<sup>142</sup> No. CV-N-99-397-PMP, 2000 WL 33709453, at \*4 (D. Nev. Mar. 21, 2000).

<sup>143</sup> *Id.* at \*18.

<sup>144</sup> 301 F.Supp. 2d 1147, 1154–55 (D. Nev. 2004).

<sup>145</sup> *Id.* at 1157.

<sup>146</sup> *Id.* at 1156.

<sup>147</sup> 277 F.3d 1361 (Fed. Cir. 2002).

<sup>148</sup> *Id.* at 1366.

permitted continuation and divisional applications to receive the benefit of an earlier-filed patent application, did not foreclose application of prosecution laches.<sup>149</sup>

### 6. Willful Infringement

In *State Contracting & Engineering Corp. v. Condotte American Inc.*, even though the defendant did not produce an opinion of counsel as to non-infringement or validity, it reasonably relied on a belief that it had the right to practice the invention based on the agreement it had with the State of Florida, which was a licensee of the invention.<sup>150</sup> The court stated that obtaining the opinion of counsel is not necessarily the only way to avoid a finding of willful infringement.<sup>151</sup>

In *Knorr-Bremse Systeme Fuer Nutzfahrzeuge GmbH v. Dana Corp.*, the Federal Circuit sua sponte decided to hear this case en banc in order to clarify the circumstances under which an adverse inference should be drawn against an accused infringer who obtains legal advice but refuses to reveal that advice during litigation.<sup>152</sup> The court identified four issues for further briefing, for which argument was heard in early 2004:

- (1) whether it is appropriate to draw an adverse inference with respect to willful infringement where the defendant invokes attorney-client privilege or work product privilege;
- (2) whether it is appropriate to draw an adverse inference when the defendant has not obtained legal advice;
- (3) if the law regarding adverse inferences is changed, what are the consequences to this case; and
- (4) should the existence of a substantial defense to infringement be enough to defeat a charge of willful infringement, even if no legal advice was obtained?<sup>153</sup>

### 7. Inequitable Conduct

In *Dayco Products, Inc. v. Total Containment, Inc.*, the fact that a different patent examiner rejected similar claims in a different but related patent application can be material to patentability and thus factor into an inequitable conduct determination.<sup>154</sup> In this case, the applicant's patent attorney failed to disclose a different examiner's rejection of claims in a copending patent application.<sup>155</sup> The Federal Circuit concluded that this was material information: "We hold that a contrary decision of another examiner reviewing a substantially similar claim meets the *Akron Polymer* reasonable examiner' threshold materiality test."<sup>156</sup> However, the Court remanded for a

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<sup>149</sup> *Id.*

<sup>150</sup> 346 F.3d 1057, 1065 (Fed. Cir. 2003).

<sup>151</sup> *Id.* at 1064.

<sup>152</sup> 344 F.3d 1336, 1336–37 (Fed. Cir. 2003).

<sup>153</sup> *Id.*

<sup>154</sup> 329 F.3d 1358, 1368 (Fed. Cir. 2003).

<sup>155</sup> *Id.* at 1361.

<sup>156</sup> *Id.* at 1368; *Akron Polymer Container Corp. v. Exxel Container, Inc.*, 148 F.3d 1380, 1382 (Fed. Cir. 1998). "In *Akron Polymer*, under facts substantially similar to the facts here, the court determined

determination of intent to deceive, which was lacking in the record.<sup>157</sup> The Court declined to resolve which standard for materiality should be applied.<sup>158</sup>

In *Hoffmann-La Roche, Inc. v. Promega Corp.*, inventors who used past tense in a patent application to describe an experiment that had never been performed potentially committed inequitable conduct.<sup>159</sup> The patent application described an example procedure for repeatedly refining a bacterial culture.<sup>160</sup> The example used past tense phrases such as “[a]ctive fractions with no detectable nucleases *were pooled* and run . . . . The *results show* a single 88 kd band . . . . Example VI *was found to be free* of any contaminating Taq endonuclease and exonuclease activities.”<sup>161</sup> The past tense was used more than seventy-five times in explaining the protocol.<sup>162</sup> The inventor later admitted that he had never performed the example as described.<sup>163</sup> After concluding that the disclosure constituted misrepresentation, the Federal Circuit upheld the district court’s finding that it was material and that it was intentional, since the inventors provided no explanation as to why the past tense was used.<sup>164</sup> However, the Federal Circuit vacated and remanded because some of the other district court findings were not upheld.<sup>165</sup>

In *Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, a patent on the TAXOL<sup>®</sup> cancer drug was held unenforceable because the applicants failed to disclose to the Patent Office an article that was published by the inventors.<sup>166</sup> Although the article was not prior art, it cast doubts on the enablement of the claims because it stated that certain chemicals relied upon in the patent application were unstable.<sup>167</sup> Although the patent examiner had independently uncovered the article, he did not place his initials on the form indicating that he had considered the article.<sup>168</sup> The applicants’ French patent agent knew about the article but failed to provide it to the Patent Office or to the U.S. patent attorney.<sup>169</sup>

### 8. Unjust Enrichment & Patent Preemption

In *University of Colorado Foundation, Inc. v. American Cyanamid Co.*, a claim for unjust enrichment based on filing a patent application for an invention that was attributable to another person was not preempted under the patent laws.<sup>170</sup> The

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that the requisite intent could not be inferred because the patentee did “disclose the existence of the [the second] application to the [first] application’s examiner, and thus put the PTO on notice of the copendency of the two applications.” *Dayco*, 329 F.3d at 1366.

<sup>157</sup> *Dayco*, 329 F.3d at 1368.

<sup>158</sup> *Id.* at 1363–64 (under the old rules, the “reasonable examiner” test was applied; the new rules adopt a “prima facie case of unpatentability” or “refutes or is inconsistent with a position that the applicant takes” standard).

<sup>159</sup> 323 F.3d 1354, 1363–66 (Fed. Cir. 2003).

<sup>160</sup> *Id.* at 1364.

<sup>161</sup> *Id.* at 1365 (emphasis added).

<sup>162</sup> *Id.* at 1364 (emphasis added).

<sup>163</sup> *Id.*

<sup>164</sup> *Id.* at 1367.

<sup>165</sup> *Id.* at 1372.

<sup>166</sup> 326 F.3d 1226, 1242 (Fed. Cir. 2003).

<sup>167</sup> *Id.* at 1234.

<sup>168</sup> *Id.* at 1236.

<sup>169</sup> *Id.* at 1231.

<sup>170</sup> 342 F.3d 1298, 1308 (Fed. Cir. 2003).

defendant incorporated confidential materials from the plaintiff into a patent application and obtained a patent without listing the plaintiff as an inventor.<sup>171</sup> The plaintiff was awarded millions of dollars in damages under an unjust enrichment theory.<sup>172</sup> The Federal Circuit concluded that the claim was not preempted under the patent law, because it did not create new patent rights or extend the scope of federal patent rights to cover otherwise unpatentable ideas.<sup>173</sup> Unlike the boat hulls involved in the Supreme Court's *Bonito Boats* decision,<sup>174</sup> the invention in *University of Colorado* was patentable.<sup>175</sup>

### 9. Procedure

In *Pandrol USA, LP v. Airboss Railway Products, Inc.*, a party did not waive an invalidity defense by failing to raise it in response to a motion for summary judgment of infringement.<sup>176</sup> Although the Federal Circuit upheld the grant of summary judgment for infringement, it vacated the district court's ruling that Airboss had waived the affirmative defense of invalidity by failing to raise it in response to Pandrol's motion for summary judgment.<sup>177</sup>

### 10. Patents in Standard-Setting Organizations

In *Rambus Inc. v. Infineon Technologies AG*, the Federal Circuit overturned a jury verdict that Rambus committed fraud under Virginia law by failing to disclose to a standards-setting organization that it held patents relating to memory devices.<sup>178</sup> Rambus participated in JEDEC, a standard-setting body in the electronics industry.<sup>179</sup> JEDEC had a written patent policy encouraging the adoption of standards free of patented items, and requiring members to disclose patents and patent applications "related to" the standardization work of its various committees.<sup>180</sup> The Federal Circuit interpreted the patent policy to require disclosure only if a license under the patent claims was required to practice the standard.<sup>181</sup> Judge Prost dissented, concluding that the patent policy contained a broader disclosure requirement.<sup>182</sup>

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<sup>171</sup> *Id.* at 1300.

<sup>172</sup> *Id.* at 1312.

<sup>173</sup> *Id.* at 1307–08.

<sup>174</sup> *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141 (1989).

<sup>175</sup> *Id.* at 1307.

<sup>176</sup> 320 F.3d 1354, 1365 (Fed. Cir. 2003).

<sup>177</sup> *Id.* at 1369.

<sup>178</sup> 318 F.3d 1081, 1105 (Fed. Cir. 2003).

<sup>179</sup> *Id.* at 1085.

<sup>180</sup> *Id.*

<sup>181</sup> *Id.* at 1100.

<sup>182</sup> *Id.* at 1118 (Prost, J., dissenting).

### 11. *Standing to Sue for Infringement*

In *Paradise Creations, Inc. v. UV Sales, Inc.*, a corporation lacked standing to sue for patent infringement because, at the time it obtained an exclusive patent license and filed the lawsuit, it was administratively dissolved under Florida law for failing to file its annual report.<sup>183</sup> The Federal Circuit upheld dismissal of the lawsuit even though Paradise had been reinstated as a corporation after the lawsuit was filed.<sup>184</sup> According to the Federal Circuit, standing must be present at the inception of the lawsuit.<sup>185</sup>

### 12. *State Immunity from Patent Infringement*

In *Regents of the University of New Mexico v. Knight*, after the University of New Mexico brought suit against two faculty members to force them to assign certain patents developed while at the university, the faculty members filed counterclaims for compensation under various theories.<sup>186</sup> The district court dismissed the counterclaims as being barred under the Eleventh Amendment sovereign immunity clause.<sup>187</sup> The Federal Circuit vacated the decision, concluding that by filing suit in federal court the university waived its sovereign immunity with respect to all compulsory counterclaims (i.e., those arising from the same transaction or occurrence), and remanded to the district court for a determination as to which counterclaims should be reinstated.<sup>188</sup>

### 13. *Hatch-Waxman Act*

In *Warner-Lambert Co. v. Apotex Corp.*, it was held not to be an act of infringement to submit an Abbreviated New Drug Application (“ANDA”) for approval to market a drug for a use that was not covered by an existing patent.<sup>189</sup> Warner-Lambert obtained FDA approval to market its patented drug for use in treatment of seizures in adults with epilepsy.<sup>190</sup> Warner-Lambert also had a second patent covering use of the same drug for use in treating neurodegenerative diseases.<sup>191</sup> Apotex filed an ANDA seeking approval to market a generic version of the drug for the treatment of epilepsy after Warner-Lambert’s first patent expired.<sup>192</sup> Warner-Lambert sued, alleging that Apotex would induce infringement of its second patent directed to treating neurodegenerative diseases with the drug.<sup>193</sup> The Federal Circuit held that Warner-Lambert could not assert infringement by alleging that the generic manufacturer would induce infringement of

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<sup>183</sup> 315 F.3d 1304, 1310 (Fed. Cir. 2003).

<sup>184</sup> *Id.*

<sup>185</sup> *Id.* at 1308.

<sup>186</sup> 321 F.3d 1111, 1115 (Fed. Cir. 2003).

<sup>187</sup> *Id.* at 1124.

<sup>188</sup> *Id.* at 1127.

<sup>189</sup> 316 F.3d 1348, 1354 (Fed. Cir. 2003); *see generally* 35 U.S.C. § 271 (e)(2) (2003); 21 U.S.C. § 321 (aa) (2003).

<sup>190</sup> *Warner-Lambert*, 316 F.3d at 1352.

<sup>191</sup> *Id.* at 1351.

<sup>192</sup> *Id.* at 1352.

<sup>193</sup> *Id.* at 1353.

one of its other patents that did not cover the use for which the generic drug was being approved.<sup>194</sup>

In *Allergan, Inc. v. Alcon Laboratories, Inc.*, the Federal Circuit held that the owner of a patent for a non-FDA approved method of using a drug cannot sue a generic drug manufacturer for infringement based on the generic manufacturer's filing of an ANDA that seeks approval for a use different from that claimed in the patent.<sup>195</sup> Allergan's two patents cover a method of using an unpatented drug for (1) protecting the optic nerve and (2) neural protection.<sup>196</sup> Neither of these uses of the unpatented drug had been approved by the FDA.<sup>197</sup> Alcon submitted an ANDA to the FDA seeking approval for a generic use of the unpatented drug to reduce interocular pressure, a use not claimed in Allergan's patents.<sup>198</sup> Allergan sued, claiming that Alcon's proposed use would induce infringement of its patents because doctors would prescribe the drug for Allergan's patented uses.<sup>199</sup> The Federal Circuit held that this case was controlled by its earlier decision in *Warner-Lambert* (see above), and that Allergan could not base a claim on uses not approved under the asserted patent.<sup>200</sup>

In *Apotex, Inc. v. Thompson*, the court found that the FDA was not required to substantively review patents before listing them in its "Orange Book."<sup>201</sup> SmithKline had listed one of its patents in the Orange Book with respect to one of its FDA-approved drugs.<sup>202</sup> After a generic competitor filed a request with the FDA to produce a generic version of the drug, SmithKline listed additional patents in the Orange Book with respect to the drug and sued the generic competitor for patent infringement.<sup>203</sup> The competitor sued the FDA to force removal of the additional patents, claiming that they did not cover the drug that was originally approved by the FDA.<sup>204</sup> The Federal Circuit held that the FDA's regulation, under which it did not substantively examine Orange Book listings, was reasonable in light of the fact that the Hatch-Waxman Act did not require the FDA to examine the listings.<sup>205</sup>

#### *D. FTC Actions Involving Patents*

##### *1. Rambus*

The FTC has filed an antitrust case against Rambus, charging that the company deceived an industry standard-setting organization by failing to disclose that it held key

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<sup>194</sup> *Id.* at 1362.

<sup>195</sup> 324 F.3d 1322, 1334 (Fed. Cir. 2003).

<sup>196</sup> *Id.* at 1324.

<sup>197</sup> *Id.*

<sup>198</sup> *Id.*

<sup>199</sup> *Id.* at 1329.

<sup>200</sup> *Id.* at 1334.

<sup>201</sup> 347 F.3d 1335, 1349 (Fed. Cir. 2003); see generally 21 U.S.C 355 § (c)(2) (2000).

<sup>202</sup> *Apotex*, 347 F.3d at 1349.

<sup>203</sup> *Id.*

<sup>204</sup> *Id.* at 1340.

<sup>205</sup> *Id.* at 1352.

patents involving memory technology.<sup>206</sup> This case was dismissed on February 24, 2004 by an administrative law judge, but is being appealed.<sup>207</sup> In a related case, the Federal Circuit held that Rambus did not commit fraud under Virginia law by failing to disclose the patents.<sup>208</sup>

## 2. *Unocal*

The FTC filed a complaint against Unocal in March 2003, alleging that its actions in not disclosing its patents to the California Air Resources Board during its rule-making for reformulated gasoline were anticompetitive.<sup>209</sup> Unocal's patents broadly cover cleaner-burning gas mandated by California.

## 3. *Schering-Plough, Upsher-Smith, American Home Products*

On December 8, 2003, the FTC ruled that the companies above had entered into illegal agreements to delay entry of lower-cost generic drugs for Schering's prescription drug K-Dur 20, used to treat low blood-potassium levels.<sup>210</sup> Schering and Upsher settled patent infringement litigation under an agreement by which Schering, the patent owner, paid Upsher \$60 million in exchange for Upsher's agreement not to enter the generic market for the drug until four years later, even though the thirty month stay caused by the patent litigation would have ended years earlier.<sup>211</sup> The FTC found that this was anti-competitive.<sup>212</sup> A similar agreement between Schering and American Home Products was also found to be anti-competitive.<sup>213</sup>

## 4. *The FTC's "White Paper"*

The FTC issued a report entitled *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, which makes various recommendations, most of which appear to have the effect of weakening patents by making them easier to invalidate.<sup>214</sup>

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<sup>206</sup> *In re Rambus Inc., a corporation*, Docket No. 9302, Federal Trade Commission (Feb. 23, 2004), available at <http://www.ftc.gov/os/adjpro/d9302/index.htm> (last visited April 13, 2004).

<sup>207</sup> *Id.*

<sup>208</sup> *Rambus v. Infineon Techs., Inc.*, 318 F.3d 1081 (Fed. Cir. 2003).

<sup>209</sup> *In re Union Oil Co. of Cal., a corporation*, Docket No. 9305, Federal Trade Commission (March 4, 2003).

<sup>210</sup> *In re Schering-Plough Corp., a corporation*, Docket No. 9297, Federal Trade Commission, 27 (Dec. 8, 2003).

<sup>211</sup> *Id.* at 16.

<sup>212</sup> *Id.* at 169.

<sup>213</sup> *Id.* at 170.

<sup>214</sup> *The Proper Balance of Competition and Patent Law and Policy*, A Report by the Federal Trade Commission (October 2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (last visited Apr. 6, 2004).



## V. HOW TO “FESTO-PROOF” YOUR PATENT APPLICATION

The Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kabushiki Co.* held that prosecution history estoppel applies to any claim amendment made to satisfy any requirement of the patent statute, not just those made to avoid the prior art.<sup>215</sup> However, the Supreme Court rejected the Federal Circuit’s “bright line” rule, holding that the estoppel should not completely bar assertion of equivalents infringement except under certain circumstances.<sup>216</sup> In short, the Supreme Court held that the patentee should bear the burden of showing that a particular amendment does not surrender the particular equivalent in question, and that “[t]he patentee must show that at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent.”<sup>217</sup> The Court explained:

There are some cases, however, where the amendment cannot reasonably be viewed as surrendering a particular equivalent. The equivalent 1) *may have been unforeseeable at the time of the application*; 2) *the rationale underlying the amendment may bear no more than a tangential relation to the equivalent in question*; or 3) *there may be some other reason suggesting that the patentee could not reasonably be expected to have described the insubstantial substitute in question*. In those cases the patentee can overcome the presumption that prosecution history estoppel bars a finding of equivalence.<sup>218</sup>

Following the Supreme Court’s *Festo* ruling, the Federal Circuit stated that applicants may only rely on evidence in the public file history in order to rebut the presumption of estoppel, and that extrinsic evidence such as an attorney’s after-the-fact affidavit would be inadmissible.<sup>219</sup> In that case, the Federal Circuit also reaffirmed the principle that voluntary amendments, as well as amendments arising from a patent examiner’s rejection, could create estoppel.<sup>220</sup>

On remand from the Supreme Court, the Federal Circuit further interpreted the Supreme Court’s opinion in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*<sup>221</sup> The Federal Circuit ruled that:

(1) whether the presumption of surrender had been rebutted was a purely legal issue, despite potential fact issues regarding the level of skill in the art;

(2) the specific factors to be considered in evaluating the rebuttal would be developed on a case-by-case basis;

(3) unforeseeability is an objective (not subjective) inquiry relating to what a person of ordinary skill in the art would have foreseen at the time the amendment was made;

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<sup>215</sup> 535 U.S. 722, 736 (2002).

<sup>216</sup> *Id.* at 737.

<sup>217</sup> *Id.* at 749.

<sup>218</sup> *Id.* at 740–42 (emphasis added).

<sup>219</sup> *Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1356 (Fed. Cir. 2003) (“[O]nly the public record of the patent prosecution, the prosecution history, can be a basis for such a reason.”).

<sup>220</sup> *Id.*

<sup>221</sup> 344 F.3d 1359 (Fed. Cir. 2003).

- (4) later-developed technology is generally not foreseeable for purposes of rebuttal;
- (5) earlier-developed technology is likely to have been foreseeable; and
- (6) a district court may hear expert testimony and consider extrinsic evidence regarding whether an alleged equivalent would have been foreseeable, but "tangential relation" and "some other reason" reasons should be determined based solely on the prosecution history.

Additionally, the Federal Circuit held that the "tangential relation" reason could not be relied upon if the alleged equivalent was present in the prior art that the amendment was intended to overcome. The court remanded to the district court to determine whether one of ordinary skill would have thought that a single two-way sealing ring was an objectively unforeseeable equivalent of two one-way sealing rings.

Other recent Federal Circuit cases have given an additional gloss to these principles. In *Ranbaxy Pharmaceuticals, Inc. v. Apotex, Inc.*, the Federal Circuit held that rewriting a dependent claim in independent form in response to an examiner's objection constitutes a narrowing amendment for purposes of prosecution history estoppel, thus giving rise to a rebuttable presumption that the alleged equivalent was surrendered.<sup>222</sup> The Federal Circuit concluded based on the evidence before it that the alleged equivalent (acetic acid) was likely foreseeable at the time of the amendment, and the patent owner likely surrendered coverage for the equivalent.<sup>223</sup> In *Deering Precision Instruments, LLC v. Vector Distribution Systems, Inc.*, Deering was found to have narrowed its claims by canceling broader claims and substituting narrower claims.<sup>224</sup> The Federal Circuit remanded to determine whether Deering could rebut the *Festo* presumption that the alleged equivalents had been surrendered.<sup>225</sup>

Although there does not yet appear to be a post-*Festo* decision applying *Festo* in the context of argument-based estoppel, it is this author's opinion that argument-based estoppel will receive the same *Festo* treatment as amendment-based estoppel. There are several pre-*Festo* cases where the Federal Circuit has made clear that it will treat amendment-based estoppel and argument-based estoppel in the same manner.<sup>226</sup>

The primary difference between argument-based estoppel and amendment-based estoppel, however, is the circumstance that will give rise to the presumption. Under *Festo*, a narrowing amendment made for a reason related to patentability will give rise to a rebuttable presumption that the equivalent in question is barred. Argument-based estoppel, however, does not arise unless the applicant made a "clear and unmistakable surrender" of subject matter during prosecution.<sup>227</sup> Presumably, the question in

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<sup>222</sup> 350 F.3d 1235, 1240 (Fed. Cir. 2003).

<sup>223</sup> *Id.* at 1241. Because the appeal was from the denial of a preliminary injunction, additional evidence could presumably be introduced during further proceedings in the district court.

<sup>224</sup> 347 F.3d 1314, 1327 (Fed. Cir. 2003).

<sup>225</sup> *Id.*

<sup>226</sup> *See, e.g.*, *Pharmacia & Upjohn Co. v. Mylan Pharm.*, 170 F.3d 1373 (Fed. Cir. 1999); *Elkay Mfg. v. Ebco Mfg.*, 192 F.3d 973, 979 (Fed. Cir. 1999) ("Arguments made during the prosecution of a patent application are given the same weight as claim amendments."); *Abbott Labs. v. Dey, L.P.*, 287 F.3d 1097 (Fed. Cir. 2002) (finding no estoppel but noting that argument-based estoppel and amendment-based estoppel are treated interchangeably).

<sup>227</sup> *See, e.g.*, *Eagle Comtronics Inc. v. Arrow Comm. Labs.*, 2002 U.S. App. LEXIS 19150 (Fed. Cir. 2002); *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000).

argument-based estoppel cases would be whether the applicant could have crafted an argument that would have avoided surrendering a foreseeable alternative.

#### WHAT'S A PATENT PRACTITIONER TO DO?

1. *Conduct a thorough prior art search.* Filing a patent application with claims when you have no idea what is the closest prior art is like shooting in the dark. Although it adds time and cost to the patent application, finding prior art before the examiner does may avoid the need to make major claim amendments down the road. If your client does not want to pay for a prior art search, conduct a quick keyword search on the free PTO web site, and ask the inventor to provide you with copies of the closest prior art. A side benefit of conducting a prior art search is that it may enable you to file a petition to make special, expediting the examination of your patent application.<sup>228</sup>

2. *Use the prior art to identify alternative embodiments.* Given the Supreme Court's warning that estoppel may arise unless the equivalent was "unforeseeable," prior art in the same field as the invention will likely be used against you as evidence in litigation that a particular equivalent was foreseeable. Put the foreseeable variations found in the prior art for the most critical inventive elements into your patent application, and claim them. Recall *Johnson & Johnston*, where disclosed but unclaimed embodiments are "dedicated to the public."<sup>229</sup>

3. *Ask the inventor to think of all possible alternatives.* One technique is to ask the inventor(s) to "design around" the broadest claim you have drafted, allowing you to tweak it or add new claims to cover the design arounds. Again, this will increase the cost of the patent application, both in attorney time and inventor time. Explain to the inventors that if you do not perform this exercise, the patent may be worthless because an infringer could get around the patent by using a "foreseeable" alternative for one of the claimed elements. You do not want the inventor to admit on the witness stand that he knew of a foreseeable alternative but never mentioned it to his patent attorney because the attorney never asked him about such alternatives.

4. *Make sure all embodiments and variations are claimed.* This is not strictly a *Festo* problem, but practitioners who disclose "foreseeable" alternatives must remember to claim them, lest they will be waived.<sup>230</sup>

5. *Leave out "objects of the invention" and similar discussions.* Some practitioners feel obligated to list or discuss in the specification various "objects" or "goals" of an invention. The accused infringer will demonstrate that its device lacks some or all of the "goals" listed in the patent in an attempt to show that it is substantially different or that the patent is limiting. Although this does not directly implicate *Festo*, its effect is similarly limiting.<sup>231</sup>

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<sup>228</sup> See U.S. Patent and Trademark Office, MANUAL OF PATENT EXAMINING PROCEDURE § 708.02 (8th ed. 2003).

<sup>229</sup> *Johnson & Johnston Assoc., Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1051 (Fed. Cir. 2002).

<sup>230</sup> See *id.*

<sup>231</sup> See, e.g., *Unique Concepts Inc. v. Brown*, 939 F.2d 1558 (Fed. Cir. 1991) (no infringement under the doctrine of equivalents because one of the "objects" of the invention stated that it was intended to be useful for a "do-it-yourselfer"); *Alloc Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361 (Fed. Cir. 2003) (relying on "objects of the invention" to narrowly interpret the claims).

6. *Do not criticize the prior art in the application.* Criticism of a particular feature in a patent application may prevent a patentee from reclaiming that subject matter through the doctrine of equivalents.<sup>232</sup> Again, this is not strictly a *Festo* problem, but nevertheless limiting statements in the specification can be treated as a form of estoppel.

7. *Define and then use broad terminology for the claims.* Rather than relying on assumptions (including common usage and dictionary definitions) for terminology used in the claims, define terms in the specification broadly and then use the broad terminology in the claims. For example, rather than reciting that a method operates on a “file,” you can instead define an “object” as “a file, directory, collection of bits or data, or any other grouping of information,” and then use “object” in the claim rather than “file.” This avoids an infringer’s argument that “file” has a narrow definition lacking an equivalent in the accused device. It also avoids the need to show equivalence in the first place, thus avoiding prosecution history estoppel.

8. *Consider, but do not exclusively rely on, means-plus-function claims.* Means-plus-function claims provide built-in equivalence that can be proved as *literal* infringement, rather than relying on the doctrine of equivalents. Make sure you also include other independent claims that do not rely on means-plus-function clauses.

9. *Have a second patent attorney review the claims.* No matter how experienced you are, a second patent attorney with a fresh set of eyes may spot an unnecessary or unclear limitation that you had not considered. Fixing problems and ambiguities before the application is filed may avoid the need to amend the claims during prosecution. Again, it will add minimally to the cost of drafting the application, but you can explain to your client that doing so will result in a stronger patent.

10. *Try to “redefine” a claim limitation rather than “narrowing” it.* Given that prosecution history estoppel only applies to *narrowing* claim amendments, try to characterize amendments made during prosecution as “redefining” limitations made for clarity only, rather than narrowing limitations made to avoid the prior art.<sup>233</sup>

11. *Appeal more often.* This sounds obvious, but overturning an examiner’s rejection rather than acquiescing to a slightly narrowing claim may make a huge difference in patent scope when the “slightly narrowing” amendments are scrutinized under the microscope of litigation. The pendency of appeals at the Board of Appeals has been significantly reduced in the last year or so, speeding up the appeals process. Recent statistics also suggest that 30% of appeals are resolved in the appeal conference that takes place before the file is transmitted to the Board of Appeals. Moreover, recent statistics show that approximately 50% of all appeals to the Board result in at least a partial victory for the applicant.

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<sup>232</sup> *Schwing GMBH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1329 (Fed. Cir. 2002); *Alloc Inc. v. Int’l Trade Comm’n*, 342 F.3d 1361 (Fed. Cir. 2003) (pointing to criticism of the prior art in the specification).

<sup>233</sup> *See, e.g., Interactive Pictures Corp. v. Infinite Pictures Inc.*, 274 F.3d 1371 (Fed. Cir. 2001) (amending the claim term “output signals” to “output transform calculation signals” did not narrow the claim, since it merely rendered explicit what was already implicit in the claim); *Bose Corp. v. JBL, Inc.*, 274 F.3d 1354 (Fed. Cir. 2001) (fixing an antecedent basis problem in a claim did not constitute a narrowing amendment for purposes of prosecution history estoppel); *Turbocare Division of Demag Delaval Turbomachinery Corp. v. General Elec. Co.*, 264 F.3d 1111 (Fed. Cir. 2001) (explaining that a newly added claim only “redefined” the small clearance position without narrowing the claim, and prosecution history estoppel did not apply).

12. *Interview the patent examiner before filing an amendment.* If you can convince the examiner that one out of a set of arguments or amendments is persuasive during an interview, without reducing all of those reasons or amendments to writing, this leaves you with the flexibility of only relying on those amendments or arguments in the response that are likely to be persuasive with the examiner.

13. *Swear behind a reference* rather than arguing that the reference is distinguishable. Removing prior art by showing that it is not “prior” avoids estoppel altogether (i.e., no amendments and no limiting arguments).

14. *Explain amendments* as merely clarifying the scope of the invention, rather than as being required to avoid the prior art. Leaving out an explanation will give rise to a presumption that it was related to patentability, which may be virtually impossible to overcome given that the Federal Circuit has limited such explanations to those that are found in the prosecution history.