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## The Emerging Role of the Court of Customs & Patent Appeals in Import Regulation: *Astra-Sjuco, A.B. v. U.S. International Trade Commission*

In 1974 Congress amended section 337 of the Tariff Act of 1930 to allow for expanded appellate review of International Trade Commission (ITC) decisions.<sup>1</sup> The United States Court of Customs and Patent Appeals (CCPA) is now empowered to review final determinations of the

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<sup>1</sup> Tariff Act of 1930, ch. 497, § 337, 46 Stat. 703, *as amended by* Trade Act of 1974, Pub. L. No. 93-618, § 341(a), 88 Stat. 2053 (1975) (current version at 19 U.S.C.A. § 1337 (West & West Supp. 1981)). The statute reads in part as follows:

(a) Unfair methods of competition and unfair acts in the importation of articles into the United States, or in their sale by the owner, importer, consignee, or agent of either, the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, . . . are declared unlawful, and when found by the Commission to exist shall be dealt with, in addition to any other provisions of law, as provided in this section.

(b)(1) The Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative. Upon commencing any such investigation, the Commission shall publish notice thereof in the Federal Register. The Commission shall conclude any such investigation, and make its determination under this section, at the earliest practicable time, but not later than one year . . . after the date of publication of notice of such investigation.

(c) The Commission shall determine, with respect to each investigation conducted by it under this section, whether or not there is a violation of this section. Each determination under subsection (d) or (e) of this section shall be made on the record after notice and opportunity for a hearing in conformity with the provisions of subchapter II of chapter 5 of Title 5. All legal and equitable defenses may be presented in all cases. Any person adversely affected by a final determination of the Commission under subsection (d), (e) or (f) of this section may appeal such determination to the United States Court of Customs and Patent Appeals for review in accordance with chapter 7 of Title 5. Notwithstanding the foregoing provision of this subsection, Commission determinations under subsections (d), (e) and (f) of this section with respect to its findings on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the amount and nature of bond or the appropriate remedy shall be reviewable in accordance with section 706 of Title 5.

(d) If the Commission determines, as a result of an investigation under this section, that there is violation of this section, it shall direct that the articles concerned, imported by any person violating the provision of this section, be excluded from entry into the United States, unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry. . . .

(g)(1) If the Commission determines that there is a violation of this section, or

ITC on behalf of any person adversely affected by such determinations.<sup>2</sup> So far, six patent infringement cases have been brought before the CCPA under section 1337(c), of which *Astra-Sjuco, A.B. v. U.S. Int'l Trade Comm'n*<sup>3</sup> is the most recent. *Astra-Sjuco* is the fourth case to be decided on its merits and the first to present the CCPA with the issue of injury to a U.S. domestic industry.<sup>4</sup> The CCPA considered three issues: 1) whether the patent in question was valid; 2) whether the patent was infringed by respondent's product; and 3) whether there was resulting injury to the domestic industry. The court answered all three questions in the affirmative and concurred with the ITC's determination to exclude respondent's product from the United States for the duration of the patent.<sup>5</sup>

Subsection (a) of 19 U.S.C. § 1337 states that

[u]nfair methods of competition and unfair acts in the importation of articles into the United States . . . , the effect or tendency of which is to destroy or substantially injure an industry, efficiently and economically operated, in the United States, or to prevent the establishment of such an industry, . . . are declared unlawful and when found by the Commission to exist shall be dealt with, in addition to any other provisions of law, as provided in this section.

Complainant Steridyne Corporation is a domestic manufacturer of thermometer sheath packages, and the exclusive licensee under two patents held by George Poncy.<sup>6</sup> Steridyne filed a complaint with the ITC alleg-

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that, for purposes of subsection (e) of this section, there is reason to believe that there is such a violation, it shall—

(A) publish such determination in the Federal Register, and  
 (B) transmit to the President a copy of such determination and the action taken under subsection (d), (e), or (f) of this section, with respect thereto, together with the record upon which such determination is based.

(2) If, before the close of the 60-day period beginning on the day after the day on which he receives a copy of such determination, the President, for policy reasons, disapproves such determination and notifies the Commission of his disapproval, then, effective on the date of such notice, such determination and the action taken under subsection (d), (e), or (f) of this section with respect thereto shall have no force or effect.

<sup>2</sup> *Id.* § 1337(d).

<sup>3</sup> 629 F.2d 682 (C.C.P.A. 1980).

<sup>4</sup> The five previous cases to reach the CCPA are: *Stevenson v. U.S. Int'l Trade Comm'n*, 612 F.2d 546 (C.C.P.A. 1979); *Solder Removal Co. v. U.S. Int'l Trade Comm'n*, 582 F.2d 628 (C.C.P.A. 1978); *Coleco Indus., Inc. v. U.S. Int'l Trade Comm'n*, 573 F.2d 1247 (C.C.P.A. 1978); *Rohm & Haas Co. v. U.S. Int'l Trade Comm'n*, 554 F.2d 462 (C.C.P.A. 1977); *Import Motors Ltd., Inc. v. U.S. Int'l Trade Comm'n*, 530 F.2d 937 (C.C.P.A. 1975) (stay of ITC hearing pending appeal); 530 F.2d 938 (C.C.P.A. 1976) (appeal dismissed).

<sup>5</sup> 19 U.S.C. § 1337(d) (1976) provides for a so-called permanent exclusion order (PEO). Two other possible remedies are the temporary exclusion order (TEO), provided under § 1337(e), and the cease and desist order, provided under § 1337(f). The TEO is used where continued importation pending a hearing and final order would substantially damage complainant's industry. Under a TEO, the foreign goods are either excluded from entry, or allowed in only under bond. The cease and desist order was added as a result of pressure for a less drastic remedy than total exclusion. Unlike the PEO or TEO, the cease and desist order is an in personam remedy, directed at the importers and distributors themselves. The ITC has been reluctant to employ the cease and desist order because it is so easily avoided by merely switching importers.

<sup>6</sup> 629 F.2d at 683.

ing that Astra-Sjuco, a Swedish supplier of thermometer sheath packages, was exporting sheath packages into the United States which infringed the Poncy patents.<sup>7</sup> Also named as defendants were the domestic importer and the distributor of the Swedish sheath package. The ITC is authorized by 19 U.S.C. § 1337(b) and (d) to investigate any alleged unfair acts in the importation of articles into the United States, and, if appropriate, to exclude such articles from further entry. The ITC came to the conclusion that the foreign thermometer sheaths were infringing the U.S. patents and causing injury to the domestic industry, here solely Steridyne, and ordered an exclusion of the respondent's sheath packages from the United States for the life of the Poncy patents.<sup>8</sup>

Pursuant to section 1337(c), Astra-Sjuco and the domestic importers appealed the determination to the CCPA. They based their appeal on three claims: 1) that the Poncy patents were invalid;<sup>9</sup> 2) that they were not infringed;<sup>10</sup> and 3) that there was no injury to the domestic industry as a result of the importation of the Swedish sheath packages.<sup>11</sup> The court undertook a detailed examination of the respective claims of the Poncy and Astra-Sjuco patents and found that Astra-Sjuco had infringed several of the Poncy claims.<sup>12</sup> The court then considered the issue of patent validity and found, using standard patent validity tests,<sup>13</sup> that the Poncy patents were valid. Finally, the court considered the injury question and, based on the evidence in the record of the Commission's determination, it found the quantum of injury required by the statute for exclusion.<sup>14</sup>

The focus of this note will be on the injury question. To fully understand the nature of the Commission proceeding and the significance of the court's holding, however, a familiarity with the historical background of section 1337 and with the evolving role the CCPA has taken in its enforcement is necessary.

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<sup>7</sup> *Id.*

<sup>8</sup> Certain Thermometer Sheath Packages; Commission Determination and Order, 44 Fed. Reg. 45,270 (1979).

<sup>9</sup> 629 F.2d at 688.

<sup>10</sup> *Id.* at 686.

<sup>11</sup> *Id.* at 690.

<sup>12</sup> *Id.* at 688, 689. Although this discussion will not focus on the infringement issue, a brief outline of the steps used by the court in determining infringement may be helpful. The court first determined the meaning of the claims in issue by analysis of all relevant patent documents. Then the claims were "read on" or compared with, the accused product. The court found that Astra-Sjuco's thermometer sheath contained the same features as found in the claims of the Poncy patents.

<sup>13</sup> Methods for determining patent validity fall beyond the scope of this paper. Briefly, the most commonly used test and the one concerning the *Astra-Sjuco* court was that of obviousness—whether the invention would have been obvious at the time it was made to a person having ordinary skill in the art. To determine obviousness, a court will look at prior art, commercial success, and unresolved needs and failures of others solved by the patent in question. 629 F.2d at 688-89. See also *Graham v. John Deere Co.*, 383 U.S. 1 (1966) for a thorough discussion of patentability and obviousness.

<sup>14</sup> 629 F.2d at 690.

The present version of section 1337 has its roots in section 316 of the Tariff Act of 1922.<sup>15</sup> The 1922 report of the Senate Finance Committee stated that section 316 was designed to be "a more adequate protection to American industry than any antidumping statute the country has ever had."<sup>16</sup> Section 316 set out the present criteria for determining remediable unfair acts, namely, those whose "effect or tendency" is to "destroy or substantially injure" an "efficiently and economically operated" domestic industry.<sup>17</sup> The Tariff Commission, predecessor to the ITC, was empowered to investigate alleged violations and issue findings and recommendations to the President. The findings were to be conclusive, except for an elaborate provision for appeal on "questions of law" to the U.S. Court of Customs Appeals<sup>18</sup> and to the U.S. Supreme Court.<sup>19</sup> In 1930, the Supreme Court held, in the landmark case of *Frischer & Co., Inc. v. Bakelite Corp.*,<sup>20</sup> that violation of patent rights was an "unfair method of competition" covered by section 316.<sup>21</sup> Later that year, Congress substantially reenacted section 316 as section 337 of the Trade Act of 1930, removing only the explicit right of appeal to the Supreme Court, and the power of the President to impose an additional tariff on the imported product to offset the advantage gained by the unfair method.<sup>22</sup>

In the years before the 1974 amendment, judicial review of Tariff Commission decisions was infrequent<sup>23</sup> and when invoked, so circumscribed by the statute as to be essentially nugatory. According to the 1930 statute, the findings of the Commission could be appealed to the CCPA on "questions of law" only.<sup>24</sup> If the court found that additional evidence should have been taken by the Commission, and there were "reasonable grounds for failure to adduce such evidence" in the original proceedings, it could remand the case to the Commission for further taking of evidence. The Commission could then modify or reverse its earlier findings, which again would be subject to appeal as above. This last decision of the court would be final.<sup>25</sup>

The major flaw in this procedure was that the Commission's final report to the President, which included the CCPA's decision, was merely

<sup>15</sup> Tariff Act of 1922, ch. 356, § 316, 42 Stat. 943 (repealed 1930).

<sup>16</sup> S. REP. NO. 595, 67th Cong., 2d Sess. 3 (1922) at 3.

<sup>17</sup> Tariff Act of 1922, ch. 356, § 316(a), 42 Stat. 943 (repealed 1930).

<sup>18</sup> The name of the court was changed in 1929 to its present form, the U.S. Court of Customs and Patent Appeals. See Act of Mar. 2, 1929, Pub. L. No. 914, ch. 488, § 1, 45 Stat. 1475.

<sup>19</sup> Tariff Act of 1922, ch. 356, § 316(c), 42 Stat. 943 (repealed 1930).

<sup>20</sup> 39 F.2d 247 (C.C.P.A. 1930), cert. denied, 282 U.S. 852 (1930).

<sup>21</sup> *Id.* at 260.

<sup>22</sup> Tariff Act of 1930, *supra* note 1.

<sup>23</sup> Only six such cases came before the court between 1922 and 1962. See *Glidden v. Zdanok*, 370 U.S. 530 (1962). These cases are referred to, although not specifically named, in the Brief on Behalf of the Chief Judge and Associate Judges of the United States Court of Customs & Patent Appeals, *Amici Curiae in Glidden*, at 10.

<sup>24</sup> Tariff Act of 1930, ch. 497, § 337(c), 46 Stat. 703 (current version at 19 U.S.C.A. § 1337(c) (West Supp. 1981)).

<sup>25</sup> *Id.*

advisory. The President had full power to concur with or to disregard the report in his decision to select a remedy or to take no action whatsoever.<sup>26</sup> Therefore, judicial power was reduced to a review of mere advice which the President had the power to totally disregard.<sup>27</sup> The Supreme Court referred to these CCPA decisions as "extrajudicial revisory opinions."<sup>28</sup> In other words, the CCPA's review was limited to revising the Commission's recommendations, and therefore was itself advisory in nature. This characterization raised a constitutional dilemma regarding the status and jurisdiction of the CCPA. The Supreme Court in 1929 had held unequivocally that "the Court of Customs Appeals is a legislative and not a constitutional court,"<sup>29</sup> and therefore able to issue advisory opinions.<sup>30</sup> In 1958 however, Congress declared the CCPA to be an Article III court,<sup>31</sup> with jurisdiction limited to "cases and controversies," and thereby effectively removed the court's jurisdiction to hear appeals from the Tariff Commission under section 337.<sup>32</sup> The Supreme Court spoke on this issue again in the 1962 case of *Glidden v. Zdanok*,<sup>33</sup> reversing its earlier holding in *Bakelite* by declaring the CCPA to be a constitutional court.<sup>34</sup> The Court explained that Congress had originally intended the CCPA to be a constitutional court and that its declaration in 1958 merely clarified that original intent.<sup>35</sup> Justice Harlan's opinion attempted to resolve the jurisdictional quandary by finding that "[i]t does not follow . . . from the invalidity, actual or potential, of these heads of jurisdiction [over section 337 decisions] . . . that the CCPA must relinquish entitlement to recognition as an Article III court."<sup>36</sup> Justice Harlan noted the miniscule number of section 337 appeals heard by the court since the passage of the 1922 Act and added, "[c]ertainly the status of a . . . Court of Appeals would not be altered by a mere congressional attempt to invest it with such insignificant nonjudicial business . . . We think that, if necessary, the particular offensive jurisdiction, and not the

<sup>26</sup> *Id.* § 337(e) (codified at 19 U.S.C. § 1337(e) (1976)).

<sup>27</sup> See Metzger & Musrey, *Judicial Review of Tariff Commission Actions and Proceedings*, 56 CORNELL L. REV. 285, 307-08 (1971).

<sup>28</sup> 370 U.S. at 582.

<sup>29</sup> *Ex Parte Bakelite Corp.*, 279 U.S. 438, 460 (1929).

<sup>30</sup> This is in contrast to a court created under Article III of the U.S. Constitution, whose jurisdiction is limited to cases and controversies. U.S. CONST., art. III, § 2, cl. 1.

<sup>31</sup> 28 U.S.C. § 211 (1976).

<sup>32</sup> Revisory opinions on Commission recommendations are not decisions rendered in determination of cases or controversies. "Cases and controversies" have been defined as those questions presented in an adversarial form and capable of resolution through the judicial process. *Flast v. Cohen*, 392 U.S. 83, 95 (1968). It has been held traditionally that no justiciable controversy is presented to an Article III court when the parties seek only an advisory opinion. *Id.* See also *Muskrat v. United States*, 219 U.S. 346 (1911). C. WRIGHT, ON FEDERAL COURTS 34 (1st ed. 1963), states that "the oldest and most consistent thread in the federal law of justiciability is that federal courts will not give advisory opinions." See also *United States v. Fruehauf*, 365 U.S. 146 (1961), and cases cited therein.

<sup>33</sup> 370 U.S. 530 (1962).

<sup>34</sup> *Id.* at 583.

<sup>35</sup> *Id.* at 541-42.

<sup>36</sup> *Id.* at 582.

[court], would fall."<sup>37</sup>

It is apparent from the language of the opinion that the Court did not completely foreclose section 337 jurisdiction. Because no appeals were brought to the CCPA between 1962 and 1974, however, the Supreme Court was denied the opportunity to remove conclusively the CCPA's section 337 revisory authority. The 1974 amendment to section 337 rendered the issue moot without the Supreme Court or the CCPA offering further commentary.<sup>38</sup>

The principal cause of the CCPA's jurisdictional controversy was its inability to review the validity of the subject patent in infringement cases under section 337. In *Frischer*, the CCPA had held unequivocally that "it [is] neither the right nor the duty of the Tariff Commission to pass upon the question" of patent validity.<sup>39</sup> The procedure thereafter established was for the Tariff Commission and the CCPA to presume the validity of the patent unless it had been previously adjudicated in a federal district court and found invalid. The situation therefore evolved into one where the patent owner would simply show the existence of his patent and an importation that infringed its claims, and would be able to get the imported item excluded. There was no need to show either validity, which was presumed, or injury to the patent holder's business.<sup>40</sup> The magnitude of the problem was vividly expressed by Judge Garrett's dissenting opinion in *Frischer*. He observed that "additional duties may be levied, or an embargo declared, based upon a claim of patent which . . . may be found to be null and void, and to have been so from the very beginning."<sup>41</sup>

Moreover, the CCPA was compelled to make its determination based solely on the often meager record of the proceedings supplied by

<sup>37</sup> *Id.* at 583. [Emphasis in original.]

<sup>38</sup> See Tariff Act of 1930, *supra* note 1, at § 337(b), (c) & (g)(2) (current version at 19 U.S.C.A. § 1337(b), (c) & (g)(2) (1976)); see also accompanying text at notes 46-50.

<sup>39</sup> 39 F.2d at 258. Judge Graham stated that the Tariff Commission was merely a fact-finding body possessing no judicial powers. He noted that Congress, in the Tariff Act of 1922, the Act which created the Tariff Commission, gave not the "slightest intimation" that its purpose was to give the Commission jurisdiction to consider the validity of a patent. Moreover, Judge Graham expressed doubt as to whether Congress even had the authority to confer "case and controversy" jurisdiction on an administrative body. *Id.* at 258. See also *In re Von Clemm*, 229 F.2d 441, 444 (C.C.P.A. 1955). The *Von Clemm* case resulted from an appeal by the respondent to the Commission's finding of a violation in Synthetic Star Sapphires and Star Rubies, T.C. Inv. No. 337-13 (1954). The CCPA held that, because no district court holding of patent invalidity was alleged, it was forced to regard the patent as valid under *Frischer* and its progeny. Regarding the infringement issue, the court noted that complainant's evidence consisted of testimony by one of its inventors who stated that, although he did not know how respondent's stones were produced, he believed they must be produced by the same process as that of complainant. This testimony, combined with respondent's failure to explain how his stones were made, was held substantial evidence of infringement. Finally, although the record revealed no actual injury to complainant, the court found that the evidence supported a "tendency" to injure. On these bases, the court ordered exclusion of the imported gemstones. 229 F.2d at 444-45.

<sup>40</sup> 229 F.2d at 445-56 (Cole, dissenting). See also 39 F.2d at 267 (Garrett dissenting).

<sup>41</sup> 39 F.2d at 267 (Garrett, dissenting).

the Tariff Commission. Because much of the crucial information revealed to the Commission was confidential business information, it would not be included in the record. The court was therefore forced to base its review upon a skeletal version of the Commission's evidence, eliminating the possibility for effective review.

In sum, before 1974, the CCPA's holdings were mere commentaries on Commission recommendations, with no legal force and based upon almost no recorded evidence. After the 1958 declaration of its status as an Article III court, the CCPA did not even have the jurisdiction to render these advisory opinions.<sup>42</sup> Furthermore, neither the Commission nor the CCPA was authorized to adjudicate the validity of the subject patent.<sup>43</sup>

The magnitude of the patent validity problem was revealed in the Commission's 1968 *Furazolidone* decision.<sup>44</sup> Contrary to previous practice, the Commission refused to wait for the results of patent validity cases pending in the District Court before making its final affirmative determination of patent infringement.<sup>45</sup> The importer did not appeal the determination. If the importer had chosen to appeal, however, the CCPA would have been faced with the dilemma created when the Supreme Court in *Zdanok* affirmed it as an Article III court. In other words, because the Commission's decision was reached without a determination of the validity of the subject patent, there would have been no case or controversy for the court to review on appeal. As a result, the court would have been required to either refuse review under Article III of the Constitution and thereby deprive the importer of his section 337 right to appeal, or accept review and make some clarifying statement as to the scope of its jurisdiction. Because the importer did not appeal, an ultimate solution was forced to await the 1974 amendment of section 337.<sup>46</sup>

The 1974 amended version of section 337, renumbered section 1337, is essentially identical to the present form of the statute. The amendment was a drastic revision that attempted to resolve 50 years of confusion that had developed around section 337. First, the amendment transformed Commission "recommendations" into "final determinations" subject to judicial review, which are binding on the parties in the

<sup>42</sup> See 370 U.S. at 582.

<sup>43</sup> See Metzger & Musrey, *supra* note 27, at 319. In order to circumvent this obstacle to review, the Commission's practice, in cases where patent validity was a crucial issue, was to defer to district court decisions regarding validity.

<sup>44</sup> *Furazolidone*, Inv. No. 337-21, T.C. Pub. No. 229 (November 1969). In 1968, petitioner Norwich Pharmacy Co. filed a complaint against certain importers of furazolidone, alleging unfair methods of competition and unfair acts in the importation and sale of the drug. Petitioner alleged infringement of certain claims of its U.S. patent. The Commission found infringement and recommended exclusion for the duration of petitioner's patent. See *Furazolidone*, Findings of Unfair Methods and Acts, 34 Fed. Reg. 18,410 (1969).

<sup>45</sup> Metzger & Musrey, *supra* note 27, at 319-20.

<sup>46</sup> Trade Act of 1974, Pub. L. No. 93-618, 88 Stat. 2053, § 341(a) (1975), *amending* Tariff Act of 1930 ch. 497, § 337, 46 Stat. 703 (1930).



absence of a presidential veto. The President can overrule a Commission determination only for "policy reasons," presumably possible conflicts with foreign policy positions.<sup>47</sup> The CCPA's jurisdictional problem was thereby obviated. Most important for purposes of this analysis, however, was the addition of the following sentence to section 1337(c): "[a]ll legal and equitable defenses may be presented in all cases." The Commission and therefore the CCPA were thus authorized to consider and decide the issue of patent validity when raised as a defense by the respondent. In addition, the CCPA was expressly vested with jurisdiction to review determinations of the Tariff Commission, renamed the International Trade Commission.<sup>48</sup> Appeals may be brought by "any person adversely affected by a final determination of the Commission under subsection (d), (e), or (f)" of section 1337.<sup>49</sup>

The 1974 amendment of section 337 altered both the characteristics of the Commission's investigations and the scope of CCPA review. Under amended section 1337(a), the Commission in a patent infringement case looks at four factors: 1) is there an unfair act in the importation or sale of the article (infringement of a valid U.S. patent); 2) is the effect or tendency of the unfair act to destroy or substantially injure a domestic industry; 3) is the domestic industry efficiently and economically operated; and 4) if there is an injurious unfair act, is it in the public interest to exclude the article from the United States?

In practice, the Commission will first examine the infringement question. If it finds infringement, it will then examine the validity of the patent, applying the standard criteria of such a determination.<sup>50</sup> After the Commission finds that infringement of a valid U.S. patent has oc-

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<sup>47</sup> President Carter vetoed the Commission's affirmative determination in the case of *Certain Welded Stainless Steel Pipe and Tube*, Inv. No. 337-TA-29, U.S.I.T.C. Pub. No. 963 (Feb. 1978), an antitrust investigation. See Office of the Special Representative for Trade Negotiations, Press Release No. 269 (April 25, 1978). The Senate report on the 1974 amendment stated that,

It is recognized . . . that the granting of relief against imports could have a very direct and substantial impact on United States foreign relations, economic and political. Further, the President would often be able to best see the impact which the relief ordered by the Commission may have upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers. Senate Committee on Finance, Trade Reform Act of 1974, S. REP. NO. 1298, 93d Cong., 2d Sess. 1,199, *reprinted in* [1974] U.S. CODE CONG. & AD. NEWS 7186, 7331.

For a more complete discussion of the present scope of the ITC's authority in the non-patent area, see Minchew & Webster, *Regulating Unfair Practices in International Trade: The Role of the United States International Trade Commission*, 8 GA. J. INT'L & COMP. L. 27 (1978).

<sup>48</sup> 19 U.S.C. § 1337(c) (1976).

<sup>49</sup> The definition of "final determination" has proven to be elusive. The Senate Finance Committee's Report on H.R. 10710 attempted to clarify the phrase as "a Commission determination which has been referred to the President under amended subsection (g) of § 337, and has been approved by the President within the 60 day period after referral of the determination." S. REP. NO. 1298, *supra* note 47, at 197, *reprinted in* [1974] U.S. CODE CONG. & AD. NEWS at 7329-30. See also discussion note 5 *supra*.

<sup>50</sup> See discussion note 13 *supra*.

curred, it will consider the third aspect of its investigation, that is, whether an injury has occurred.

The determination of injury is often the most complex facet of the investigation. The Commission first must find the existence of a domestic industry<sup>51</sup> which must be efficiently and economically operated. The industry must have suffered, or be about to suffer, an injury. The Commission then carefully examines the alleged unfair importation and the asserted injury to find the necessary causal link. Each of these issues is crucial—petitioner's claim may be rejected upon the Commission's negative determination of any one of them. Finally, even if the petitioner successfully proves an unfair act resulting in injury to his efficiently and economically operated domestic industry, he may be denied relief if the Commission determines it is not in the public interest to exclude the offending article from the United States.

The Commission begins its injury investigation by ascertaining the presence of a domestic industry. A domestic industry is defined as "the domestic operations of the patent owner, his assignees and licensees devoted to such exploitation of the patent."<sup>52</sup> A domestic industry may even be confined to the single facility of the complainant.<sup>53</sup> The efficient and economic operation of the industry is determined through such characteristics as well-equipped and modern facilities, an increase in production as compared to the rest of the domestic industry, any improvement of the product by complainant, a favorable asset/liability ratio, good credit standing, reputation among peers, and level of sales.<sup>54</sup> Examples of criteria the Commission has used to determine injury include the following: reduction in sales, idling of production facilities, decrease in employment, increased market penetration by imported goods, decline in profitability, damaging effect on the selling price of the domestic product, loss of royalties or potential royalties by the domestic patentee through licensee defection or reluctance to become a licensee, and capacity and/or intention of the foreign manufacturer or importer to penetrate the domestic market.<sup>55</sup> There generally must be more than one indica-

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<sup>51</sup> The industry need not yet be in operation to qualify. A valid type of injury is the prevention of the establishment of an industry. *See* 19 U.S.C. § 1337(a) (1976). The Commission has stated that section 1337 protects "parties which are about to commence production and for which section 337 violations would have the effect or tendency to frustrate efforts to found a business." *Certain Ultra-Microtome Freezing Attachments*, Inv. No. 337-TA-10 (1976), Comm'n Determ. at 10.

<sup>52</sup> REPORT OF THE HOUSE WAYS AND MEANS COMMITTEE ON H.R. 10710, H.R. REP. NO. 571, 93d Cong., 1st Sess. 78 (1973).

<sup>53</sup> *See, e.g.*, *Convertible Game Tables*, T.C. Pub. No. 705 (March 1974); *Lightweight Luggage*, T.C. Pub. No. 391 (April 1971).

<sup>54</sup> *Kaye & Plaia, Developments in Unfair Trade Practices in International Trade: A Review of the Third and Fourth Years under Section 337 as Amended by the Trade Act of 1974*, 61 J. PAT. OFF. SOC'Y 115, 139 (1979); *Fisher, Protection Against Unfair Foreign Competition: Section 337 of the Tariff Act of 1930*, 13 VA. J. INT'L L. 158, 171 (1972); *Lightweight Luggage*, *supra* note 53, at 3; *Ampicillion*, T.C. Pub. No. 345 (Nov. 1970) at 39-40; *In-the-Ear Hearing Aids*, T.C. Pub. No. 182 (July 1966) at 20.

<sup>55</sup> *Kaye & Plaia, supra* note 54, at 135; *Fisher, supra* note 54, at 173. *See, e.g.*, the ITC's

tion of injury present to establish a causal link between the indications and the importation. Any one of these "symptoms" might have a variety of domestic sources and alone provide too weak a link to justify a remedy as drastic as exclusion. In short, the more indications of injury a petitioner can show—all other requirements being present—the more likely the Commission is to find causation and order exclusion.<sup>56</sup>

Finally, if a violation is found under the above standards, the Commission applies the public interest test promulgated under section 1337(d). Before the ITC can order permanent exclusion of an article, it must balance protection of the U.S. patent with possible detriment to the consumer and to the economy in general. It will consider whether the item is an essential of life,<sup>57</sup> and whether the domestic industry is now and will continue to be capable of providing adequate quantities of dependable products of reasonable quality at fair prices.<sup>58</sup>

The CCPA can consider all of these issues on appeal. The court cannot review the correctness of the remedies themselves, however; the CCPA reviews only the violation determination.<sup>59</sup> Prior to the 1974 amendment, the court based the scope of its review on the so-called "substantial evidence" test.<sup>60</sup> In other words, if there was substantial evidence in the Commission's record to support the findings, the court would not overturn them.<sup>61</sup> The CCPA then altered its approach toward reviews of Customs Court decisions, adopting a "clearly contrary to the weight of the evidence" standard. Because section 1337(c)<sup>62</sup> provided that the court review ITC determinations on the same basis as it would consider an appeal from a U.S. Customs Court decision,<sup>63</sup> ITC decisions apparently were to be subject to the same "clearly contrary" standard; that is, if the Commission's decision was not clearly contrary to the weight of the evidence in the record, the court would let it stand.<sup>64</sup> The difference between the two tests is one of degree. In a case where all

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application of these criteria in *Reclosable Plastic Bags*, I.T.C. Pub. No. 801 (Jan. 1977); *Convertible Game Tables*, note 53 *supra*; *Panty Hose*, T.C. Pub. No. 471 (March 1972).

<sup>56</sup> See, e.g., *Reclosable Plastic Bags*, *supra* note 55, at 14 (injury shown under five criteria); *Convertible Game Tables*, *supra* note 53, at 17 (injury shown under seven criteria); *In-the-Ear Hearing Aids*, *supra* note 54, at 22-25 (multiple criteria present).

<sup>57</sup> *Certain Molded Golf Balls*, I.T.C. Pub. No. 897 (July 1978); *Photocubes*, I.T.C. Pub. No. 862 (Jan. 1978).

<sup>58</sup> *Reclosable Plastic Bags*, *supra* note 55, at 16.

<sup>59</sup> *Kaye & Plaia*, *supra* note 54, at 60.

<sup>60</sup> Now codified as part of the Administrative Procedure Act, 5 U.S.C. § 706(2)(E) (1976).

<sup>61</sup> See, e.g., 39 F.2d at 257.

<sup>62</sup> In *Montgomery Ward & Co., Inc. v. United States*, 499 F.2d 1283 (C.C.P.A. 1974), the CCPA refused to apply the substantial evidence standard stating, "we are [not] bound to accept the Custom Court's findings of fact whenever there is substantial supporting evidence, and we will not do so when they are clearly contrary to the weight of the evidence." *Id.* at 1285. The court found substantial evidence to support the Custom Court's findings, but "even more substantial evidence to support appellant's contentions." *Id.*

<sup>63</sup> In 1922 and 1930, however, the standard of review of a Customs Court decision was in fact that of substantial evidence, as in *Frischer*.

<sup>64</sup> See text accompanying note 62 *supra*; see also *Pollard Bearings Corp. v. United States*, 511 F.2d 568, 571 (C.C.P.A. 1975).

that is required to uphold the Commission's determination is substantial evidence, the court need only look to the prevailing party's evidence to see if it established a prima facie case. Essentially, the court would overturn the Commission's determination only if no reasonable person could have found as the Commission did. The 1974 standard implied a balancing of the parties' evidence to determine if the Commission based its decision on the stronger of the two. This allowed the CCPA somewhat more leeway to evaluate the evidence and exercise its own judgment, and created a greater possibility that ITC determinations might be overturned.

The Customs Courts Act of 1980<sup>65</sup> effected a change in the CCPA's standard of review. Section 403(d) of the Act amended 28 U.S.C. § 2601(c) to provide that an appeal from the Customs Court to the CCPA is to be sustained only if the lower court's findings are "clearly erroneous."<sup>66</sup> Furthermore, section 604 of the Act amended 19 U.S.C. § 1337(c) to return the standard of review in ITC appeals to the pre-1974 substantial evidence test found in section 706 of the Administrative Procedure Act.<sup>67</sup> In addition, the Act states that the ITC's non-adjudicative public interest findings are subject to the same substantial evidence standard.<sup>68</sup>

Six patent infringement cases have been appealed to the CCPA since 1975. The first case failed to reach the merits on the grounds that the Commission had not made a "final determination."<sup>69</sup> The second was dismissed on the grounds that even though a final determination had been reached, it had not been adverse to appellee and no injury had resulted.<sup>70</sup> The third case, and the first to be decided on the merits, was *Coleco Industries, Inc. v. U.S. International Trade Commission*.<sup>71</sup>

*Coleco Industries* was the result of petitioner's appeal of the *Certain Above-Ground Swimming Pools* investigation.<sup>72</sup> The Commission had commenced its investigation with the infringement issue. It had found no infringement of any claims of the U.S. patent by the importation of the swimming pools and therefore no section 1337 violation. The Commission therefore did not reach any further issues, including that of patent validity.<sup>73</sup> The court undertook a detailed examination of the complainant's patent and the construction of the imported items to make its own

<sup>65</sup> Customs Courts Act of 1980, Pub. L. No. 96-417, 94 Stat. 1727.

<sup>66</sup> 28 U.S.C.A. § 2601(c) (West Supp. 1981).

<sup>67</sup> 19 U.S.C.A. § 1337(c) (West Supp. 1981). See *Consolo v. Fed. Maritime Comm'n*, 383 U.S. 607, 619-20 (1976).

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

<sup>69</sup> *Import Motors Ltd., Inc. v. U.S. Int'l Trade Comm'n*, 530 F.2d 937 (C.C.P.A. 1975).

For a discussion of the "final determination" issue, see note 49 *supra*.

<sup>70</sup> *Rohm & Haats Co. v. U.S. Int'l Trade Comm'n*, 554 F.2d 462 (C.C.P.A. 1977).

<sup>71</sup> 573 F.2d 1247 (C.C.P.A. 1978).

<sup>72</sup> I.T.C. Inv. No. 337-TA-25 (1977).

<sup>73</sup> The court suggested that the Commission in the future decide on all appealable issues presented to it to remove the need for remand if the court were to reverse the validity finding. 573 F.2d at 1252 n. 5.

determination of whether there was infringement. Because the Commission had gone no further, however, the court was constrained to this limited review, and affirmed the Commission's determination.

*Solder Removal Co. v. U.S. International Trade Commission*<sup>74</sup> reached the court four months later. Petitioner had appealed from the Commission's negative determination in the *Certain Solder Removal Wicks* investigation.<sup>75</sup> The Commission had considered only the validity issue, and made its determination of no violation solely on the basis of the invalidity of the subject patent.<sup>76</sup> The court first articulated its "contrary to the weight of the evidence" standard of review pursuant to section 1337(c). The court noted that "[t]he 'substantial evidence' standard is particularly inapplicable to judicial review of patent validity under section 337."<sup>77</sup> The court then considered the claims of the subject patent and the expert testimony in the Commission record and found that the Commission's findings were not against the weight of the evidence, that these findings revealed no section 1337 violation, and affirmed the ITC determination.

The third section 1337 case in which the court reached the merits was *Stevenson v. ITC*,<sup>78</sup> decided in late 1979. Petitioner had appealed the Commission's termination of the investigation into *Certain Skateboards and Platforms Therefor*,<sup>79</sup> because of a no-violation determination. *Stevenson* was another Commission determination based solely on patent validity, thereby again limiting CCPA review to only one of the many potential aspects of a section 1337 patent infringement case. The court examined the evidence on record to determine if the weight of the evidence supported the ITC's finding of patent invalidity.<sup>80</sup> The court found no evidence to support the holding, but found substantial evidence to the contrary. The court therefore found the Commission determination to be clearly against the weight of the evidence, and so reversed the finding of no violation. The case was remanded to the Commission for further investigation into the issues of infringement and injury.

*Astra-Sjuco* is the most recent and far-reaching CCPA section 1337 patent decision. The Commission had found infringement of the U.S. patent and therefore had continued its investigation into the issues of validity and injury. It found both validity of the patent and a sufficient causal link between the alleged injury and the importation to order ex-

<sup>74</sup> 582 F.2d 628 (C.C.P.A. 1978).

<sup>75</sup> I.T.C. Inv. No. 337-TA-26 (1977).

<sup>76</sup> The issue was again that of obviousness. The court also repeated its admonition to the Commission to consider all appealable issues. 582 F.2d at 632 n. 6.

<sup>77</sup> *Id.* at 632. The court noted that since there is some prior art to be found in the case of virtually every patent which could constitute "substantial evidence" under the old standard, "effective judicial review of Commission invalidity holdings would be nullified . . ." *Id.*

<sup>78</sup> 612 F.2d 546 (C.C.P.A. 1979).

<sup>79</sup> Inv. No. 337-TA-37 (1978).

<sup>80</sup> 35 U.S.C. § 282 (1976) states that a patent shall be presumed valid. A long line of cases, beginning in 1840 with *Philadelphia & T. R. Co. v. Stimpson*, 39 U.S. 448 (1840) and up to the present, have held that this presumption may only be overcome by "proof beyond a reasonable doubt," "clear and convincing evidence," or some other equally heavy burden.

clusion of the import for the life of the patent.<sup>81</sup> The appeal thus presented the court with its first opportunity to consider all the aspects of a section 1337 patent infringement case.

In its decision, the CCPA combined a thorough review of the Commission's and presiding officer's findings with its own examination of the evidence to determine if the findings on infringement and validity were clearly supported by the weight of the evidence. The court's discussion of the injury issue, however, seems to be somewhat less thorough. The court reviewed and accepted as valid indicia of injury and tendency toward injury Steridyne's alleged declining profitability, its lost sales and customers, the foreign manufacturer's large production and sales capacity, and Steridyne's provable loss of future sales. All of these criteria are apparently authorized by the ITC regulations,<sup>82</sup> and were given proper weight by the court. The court was also satisfied, however, by what it felt was persuasive causation evidence. The evidence was substantially that the foreign importer used somewhat similar packaging, solicited Steridyne's customers—at least one of whom switched products—and captured forty percent of Steridyne's market in its first year. Additionally, Steridyne experienced its decline in profits at the same time the foreign product was establishing itself in the market. Finally, the court made only the briefest reference to the appellant's claims and evidence. The court then affirmed because "the Commission's affirmative determination of injury to an industry is supported by substantial evidence in the record."<sup>83</sup>

Certain difficulties with the *Astra-Sjuco* court's injury review are apparent. First, the court neglected completely to consider the efficiency or economical operation of the U.S. industry and the public interest criteria as required by sections 1337(a) and (d).<sup>84</sup> It failed to consider the crucial "why" of appellant's notable commercial success in such a brief time. The extreme nature of the effects on petitioner's industry in itself should

<sup>81</sup> 629 F.2d at 690.

<sup>82</sup> 19 C.F.R. § 210.1-.61 (1980).

<sup>83</sup> 629 F.2d at 690. Appellants' no-injury argument before the Commission rested on two grounds: 1) Steridyne was able only to show specific lost sales in the amount of \$815; and 2) Steridyne's lost profits could be attributed mainly to consumer difficulty in using the product, the increasing popularity of electronic thermometers, and the result of recent litigation against Johnson & Johnson, which required Steridyne to limit its production. Thermometer Sheath Packages, Inv. No. 337-TA-56, U.S.I.T.C. Pub. No. 992 (July 1979), Recommended Determination at 54, Commission Determination at 26. The Presiding Officer found, however, that a preponderance of the evidence supported petitioner's theory of its lost profits rather than appellants'. Recommended Determ. at 54-55. Indicia of injury found by the Presiding Officer include, in addition to lost sales, appellants' large production capacity and massive sales force as compared to that of Steridyne. *Id.* at 55-56. The Commission affirmed the Presiding Officer's findings based on a preponderance of the evidence in the record. Comm'n Determ. at 27. It also found no public interest factors which would preclude issuing an exclusion order. *Id.* at 29.

<sup>84</sup> 19 U.S.C. § 1337(d) (1976) requires the Commission to consider the effect of any exclusion order on "the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers . . . ."

have raised some eyebrows.<sup>85</sup> Finally, the court's resurrection of the substantial evidence test, a standard of review abandoned by the court in 1975, was surprising. This decision was reached before Congress approved the substantial evidence standard in the Customs Courts Act of 1980.<sup>86</sup>

After the extensive review given the infringement and validity issues, the court gave the injury issue rather short shrift and then applied a less rigorous and at the time apparently discarded standard of review. This approach seems to indicate that of the three facets of the determination, the court felt that its duty of review with regard to injury was the least stringent. It appeared willing to summarily concur with the Commission in the absence of a glaring inconsistency in the record.<sup>87</sup> Perhaps because the finding of injury was essentially unanimous at the ITC level,<sup>88</sup> the court saw no need for detailed reconsideration of the issue. Yet the fact of unanimity below has never been grounds for limiting appellate review. Certainly, Steridyne's brief presented a bleak picture of the company's fortunes since the imported product appeared on the scene. Steridyne's counsel would be remiss if it did not present so convincing a case. Yet for the court merely to accept this evidence as alleged without the statutorily-required consideration of respondent's evidence and the other issues, seems an abdication of its responsibility to protect the public as well as the patent-holder. The dramatic shift of customers from one product to the other in such a short period of time should indicate something to the court other than injury to the patent-holder. Were the domestic thermometer sheaths overpriced? Were they in adequate supply, and of good quality? A much more stringent and inclusive standard of review is called for in this and all future appeals if the spirit of the public interest test of section 1337(d), (e) and (f) is to be fulfilled.

*Astra-Sjuco* is the first case to present the CCPA with an injury issue.

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<sup>85</sup> Aside from capturing 40% of Steridyne's market in the first year, one of Steridyne's major customers bought over one million of the foreign product and one of its sales representatives also switched products. 629 F.2d at 690.

<sup>86</sup> Customs Courts Act of 1980, *supra* note 65, at § 604 (codified at 19 U.S.C.A. § 1337(c) (West Supp. 1981)). The court's apparent confusion over which standard to apply may have been a motivating factor in Congress's enactment of sections 403 and 604 of the Act. Essentially, Congress retained the standard promulgated under the 1974 Act, to wit, review of ITC determinations in the same manner as in the case of appeals from Customs Court decisions. "Substantial evidence" under the Administrative Procedures Act has been authoritatively defined as "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consolidated Edison Co. v. Nat'l Labor Relations Bd., 305 U.S. 197, 229 (1938). Therefore, a holding based on anything less than substantial evidence—something less than adequate to support a reasonable conclusion—would be clearly erroneous. Thus the 1980 amendment of section 1337(c) merely remedied the ambiguous language of the 1974 version while effecting little substantive change.

<sup>87</sup> Because the existence of injury in the instant case was fairly conclusive, the court's failure to thoroughly consider the injury question did not result in an unjust decision.

<sup>88</sup> The Presiding Officer and four of the Commissioners found injury. The remaining Commissioner dissented on the ground of no infringement and did not proceed to consider the injury issue. *See* Certain Thermometer Sheath Packages, Commission Determination, *supra* note 8.

It is amply evidenced by *Astra-Sjuco* and other recent cases that the CCPA has come far since the 1930's in the review of Commission decisions. Its role is expected to continue to grow as the number of petitions brought before the Commission dramatically increases each year.<sup>89</sup> The internationalization of business and the increased authority of the ITC under the 1974 Act should transform the CCPA's role in section 1337 review from an insignificant to an important part of its jurisdiction. Along with its greater exposure to section 1337 cases should come a greater sophistication and sensitivity of approach. The CCPA has more control of ITC determinations under section 1337 than at any time in its history. It must therefore undertake a thorough review of all the complex issues presented by each infringement appeal, not just those over which the Commission itself was split. In the injury area in particular, the court must analyze domestic industry and public interest considerations as required by section 1337(a), (d), (e) and (f). The position of the importer must be more carefully examined. The standard of review is now explicitly limited to the substantial evidence test in accordance with the 1980 Act,<sup>90</sup> making the propriety of the *Astra-Sjuco* court's use of that standard a moot question. The CCPA, however, is now explicitly required to review the ITC's public interest findings in the same manner as the patent validity, infringement, and injury findings. Appeals under the 1980 Act should therefore be subject to more extensive scrutiny than that evident in *Astra-Sjuco*.

American patent holders have become accustomed to unquestioned protection of their monopolies because of traditional American technological and industrial superiority, assisted by past Commission inactivity. The domestic consumer market, however, is no longer restricted to domestic products. High quality, often superior goods are available from foreign manufacturers frequently at lower prices. The Commission is investigating a steadily increasing number of petitions under section 1337.<sup>91</sup> The CCPA, as the body entrusted with review and control of ITC determinations, must be alert to overzealous attempts to transform section 1337 into a trade barrier. Only the Commission's and in turn the CCPA's careful and thorough evaluation of the effect of an imported product on a valid domestic competitor, on the economy as a whole and

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<sup>89</sup> Between 1936 and 1968 the Commission heard only three cases and ordered no exclusions. Between 1974 and 1975, however, 71 complaints were filed, resulting in 11 exclusion orders. Fisher, *supra* note 54, at 16; Jacobs & Hove, *Remedies for Unfair Import Competition in the United States*, 13 CORNELL INT'L L. J. 1, 19 n. 116 (1980).

<sup>90</sup> 19 U.S.C.A. § 1337(c) (West Supp. 1981).

<sup>91</sup> The number of import investigations before the ITC was 93 in 1979 and 140 in 1980. 45 Fed. Reg. Annual Index (1980); 44 Fed. Reg. Annual Index (1979).



on the consumer in particular, can afford the most equitable balance between protection of patent rights and protection of the consumer interest.

—SHELLEY M. GOLDSTEIN