

PRODUCT LIABILITY

PRODUCT MANUFACTURERS, TAKE HEED: INTERNATIONAL MARKETS BRING INTERNATIONAL REGULATORY OVERSIGHT, SAFETY STANDARDS AND LIABILITY CONCERNS

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INTRODUCTION

Since 2004, the lead consumer product safety agency in the United States has been diligently entering agreements with counterparts in other nations that create mutual obligations to share information about product risks, and exchange information and expertise to further the development of compatible product safety standards. For example, under such agreements, if a consumer product fails in Greece, information about that failure will, in theory, be rapidly transmitted from country to country until Mexican or Chinese regulators learn about the problem and presumably take some corrective action. Similarly, product safety standards adopted in one nation are likely to spread throughout this network and may subsequently be applied to products wherever they are manufactured and sold. While such developments present new challenges to consumer product manufacturing interests, they also provide new opportunities.

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In this article, we describe how the U.S. Consumer Product Safety Commission (CPSC) functions in the U.S. market, and explore the agreements this independent federal agency has forged with the European Union and individual countries across the globe. In 2006, the agency established a program office dedicated to such initiatives and to “exportation” of CPSC regulatory policies, technologies and methodologies into other jurisdictions. We briefly consider, in comparison, international mechanisms for product safety regulation, and we note how current initiatives to promote uniformity in product warnings are already having a cross-border effect. Further, we analyze the potential impact of this globalization of regulatory oversight from the perspective of product liability. Our discussion is intended to demonstrate how manufacturers can potentially benefit when products must comply with a uniform set of standards to gain entry into any international port. We conclude with recommendations designed to help product manufacturers successfully engage in and benefit from this emerging regulatory paradigm.

PRODUCT REGULATION IN THE UNITED STATES

The CPSC is an independent federal agency with the authority to regulate the safety of more than 15,000 consumer products, excluding automobiles, alcohol, boats, cosmetics, drugs, food, pesticides, firearms, and tobacco.¹ Its mission is to protect the American public from unreasonable risks of injury and death from products within its purview.

The CPSC is headed by a three-member commission appointed by the president with the advice and consent of the Senate. It accomplishes its mission by identifying product hazards and taking steps to reduce those hazards. The agency develops and enforces mandatory and voluntary standards, conducts consumer outreach and education, and employs enforcement mechanisms that include product recalls and litigation. Under the Consumer Product Safety Act (CPSA), consumer product manufacturers, importers, distributors and retailers are required to report to the CPSC product defects that could create a substantial product hazard. The CPSC also researches potential safety hazards.

With recent annual budgets near \$65 million and with some 450 full-time employees, the CPSC is charged with reducing the 25,000 deaths and 33.3 million injuries related to products within its jurisdiction that occur each year in the United States at a cost of more than \$700 billion.²

Concerns about the safety of consumer product imports and a desire to help U.S. businesses compete in a global marketplace led the CPSC to

1. Congress created the agency in 1972 with passage of the Consumer Product Safety Act, 15 U.S.C.A. §§ 2051-2085 (1998 and Supp. 2006). The agency also administers the Flammable Fabrics Act, 15 U.S.C.A. §§ 1191-1204 (1998), the Poison Prevention Packaging Act, 15 U.S.C.A. §§ 1471-1476 (1998), the Federal Hazardous Substances Act, 15 U.S.C.A. §§ 1261-1278 (1998), and the Refrigerator Safety Act, 15 U.S.C.A. §§ 1211-1214 (1998). The excluded product categories are within the bailiwick of other federal agencies.

2. CPSC, *2005 Performance and Accountability Report* i, 3, 15 (2005).

begin a sustained campaign of reaching out to counterparts in other nations by means of agreements that obligate the parties to cooperate in improving product safety by:

- **Exchanging scientific, technical and regulatory information** to help ensure the quality, safety and proper labeling of consumer products;
- **Exchanging information about emerging issues** of significant public health and safety;
- **Addressing safety problems of consumer products manufactured in either the United States or the other country** and sold in the other participating country; and
- **Participating in the training of laboratory and inspection personnel** of both countries.

Those nations entering agreements of this nature with the CPSC since 2004³ include China, Taiwan, Japan and Korea (Pacific Rim); Mexico and Canada (North America); Chile (South America); Costa Rica (Central America); India (Asia); Israel (Middle East); and the European Union (Europe)—major trading partners representing nearly all global regions. These agreements are intended to “establish closer working relationships between the signatories [and] provide for a greater and more significant exchange of information regarding consumer product safety . . .”⁴ The CPSC intends to make active use of these existing agreements and to enter similar agreements with three additional countries in 2007.⁵

THE UNITED STATES/CHINA AGREEMENT—A MODEL FOR OTHER COUNTRIES?

The CPSC has established extensive product safety-based regulatory contacts with China, (*See* CPSC’s Program Plan—China, <http://www.cpsc.gov/businfo/china/china.html>) a major consumer products supplier to the U.S. market. Besides the memorandum of understanding, the CPSC agreed with its Chinese counterpart on an action plan outlining specific cooperative actions to be taken by both organizations. The action plan foresees: (1) biannual summits on product safety; (2) the establishment of working groups in priority areas; (3) the creation of an information exchange mechanism for regular exchange of information on safety issues and an urgent consultation mechanism for information exchange to respond to events threatening public safety; and (4) the development of technical cooperation, training and assistance between the parties. Working groups on cigarette lighters, electrical products, fireworks, and toys have already been established.

3. These CPSC agreements are variously referred to as a “Memorandum of Understanding,” an “Information Sharing Agreement” or a “Statement of Intent.”

4. CPSC, *2007 Performance Budget Request* 44 (2006).

5. *Id.* (however, the *Request* does not identify which three countries).

The U.S./Chinese agenda for product safety regulatory cooperative efforts is projected to be full for 2007 based on the CPSC 2007 *Performance Budget Request*:

- **Industry-specific Safety Seminars**
 - *Goal*: In 2007, staff plans to conduct one safety seminar at a trade fair in China.
- **Retail/Vendor Training Seminars**
 - *Goal*: In 2006, staff will conduct at least one safety training seminar at a scheduled vendor meeting.
- **Biennial Summit**
 - *Goal*: In 2007, staff plans to hold the second Sino-American Consumer Product Safety Summit.
- **Working Group Meetings**
 - *Goal*: In 2007, staff plans to hold Working Group Meetings in two priority product areas (*e.g.*, lighters, electrical product recalls, fireworks, toys).
- **Dialogues with Stakeholders**
 - *Goal*: In 2007, staff plans to hold one public Roundtable Meeting to discuss an aspect of CPSC's China Program.
- **China Program Plan Update**
 - *Goal*: In 2007, staff plans to update China Program Plan.

The CPSC underscored its commitment to this initiative when it created its Office of International Programs and Intergovernmental Affairs in February 2006.⁶ With a stated goal of harmonizing “the use of standards worldwide,” the office is charged with coordinating “efforts with other countries regarding safety standards development and harmonization, and inspection and enforcement coordination.”⁷ The office also works to ensure greater import compliance with recognized American safety standards and to promote CPSC regulatory policies, technologies and methodologies in other jurisdictions.

Regarding the standards development prong of the CPSC's regulatory approach, Congress has mandated that the agency adopt the voluntary product standards developed by Standards Development Organizations (SDOs) rather than develop its own mandatory standards, if the agency determines that the voluntary standard will eliminate or adequately reduce an injury risk and substantial compliance is likely.⁸ According to Congress, the voluntary approach can provide “significant ad-

6. Statement of Organization and Functions, 71 Fed. Reg. 5165 (Feb. 1, 2006) (to be codified at 17 C.F.R. pt. 1000).

7. CPSC, 2007 *Performance Budget Request* 43 (2006).

8. 15 U.S.C.A. § 2056(b) (1998), 15 U.S.C.A. § 1262(g) (2) (1998), 15 U.S.C.A. § 1193 (h)(2) (1998). The agency is also required to provide administrative and technical assistance to private standards development organizations. 15 U.S.C.A. § 2054(a)(3) and (4) (1998).

vantages over adversarial rulemaking.”⁹ And the agency has complied by working with industry and others to develop more than 300 voluntary standards and issuing only thirty-five mandatory rules between 1990 and 2005.¹⁰ Experience demonstrates that the regulated are more likely to comply with regulations they have had a hand in developing, which thereby results in more effective and efficient regulation.

In July 2006, the agency published a final rule that continues and expands a pilot program through which the public is notified and given an opportunity to comment on CPSC staff positions relating to the agency’s voluntary standards activities.¹¹ The CPSC also issued a final interpretative rule that, among other matters, indicates that compliance with voluntary product safety standards “may be relevant to the Commission staff’s preliminary determination of whether that product presents a substantial product hazard under Section 15 of the CPSA.”¹²

In light of the CPSC’s increasing reliance on the voluntary standards developed by private SDOs and its incursions into the international regulatory environment, the trend toward uniformity in product safety regulation is only likely to continue. But it remains to be seen whether this outcome is desirable. For some manufacturing interests, this is a welcome development because it will mean that one reasonably uniform product along with its labeling (*i.e.*, warnings and instructions for use) will be acceptable in multiple markets and, therefore, costs of cross-border compliance will be correspondingly reduced. Others are more skeptical, with concerns about the possible export of stringent liability standards along with regulatory requirements that favor local (*i.e.*, competitive) interests. Either way, consumer product manufacturers would be well advised to monitor the activities of SDOs that develop product safety standards with the potential to be appropriated by regulatory authorities in other countries and established as applicable industry standards of care in the world’s marketplace and courtrooms. They should also strongly consider finding more direct ways to participate—by submitting comments to the CPSC or actively joining SDO technical committee deliberations,¹³ for example.

9. 5 U.S.C.A. § 521 note (1998).

10. CPSC, *2005 Performance and Accountability Report 3* (2005).

11. Commission Involvement in Voluntary Standards, 71 Fed. Reg. 38,754 (July 10, 2006) (to be codified at 16 C.F.R. pt. 1031).

12. Substantial Product Hazard Reports, 71 Fed. Reg. 30,350 (proposed May 26, 2006) (to be codified at 16 C.F.R. pt. 1115).

13. Private standards development organizations (SDOs) in the United States are accredited by the American National Standards Institute (ANSI), which requires that SDO standards be the product of a consensus process that affords interested parties due process and is open and transparent. ANSI also accredits U.S. technical advisory groups that bring the U.S. position on standards issues to the table in international arenas such as the International Organization for Standardization (ISO). The technical committees and advisory groups that participate in standards development activities are generally composed of individuals representing consumer, governmental, academic, and private business interests. Some standards can take years to develop or revise, and the public is

INTERNATIONAL REGULATORY MECHANISMS—THE EU IN FOCUS

Just as the CPSC is attempting to unite the global community in terms of product safety, the European Union (EU) has spent several decades working to harmonize consumer product safety standards among member states. EU product safety regulation is controlled by the revised General Product Safety Directive (Directive).¹⁴ The Directive enshrines the “precautionary principle” in product safety, which empowers regulatory authorities to take protective measures against potential risks regardless whether the nature and scope of the risk have been determined with scientific certainty.¹⁵ Thus, action may be taken to ban products that could be dangerous or to recall dangerous products already on the market in the absence of clear scientific evidence that the products are unsafe.

Under the Directive, member states must ensure that producers and distributors comply with duties to produce only “safe” products by:

- Appointing an existing authority or establishing a new regulatory body with the power to enforce the Directive¹⁶;
- Developing penalties for infringements of those national provisions adopted under the Directive¹⁷;
- Taking action when measures taken by producers and distributors are insufficient, *i.e.*, by banning marketing and by initiating product withdrawals and recalls¹⁸;
- Ensuring that monitoring programs are introduced by relevant authorities to maintain the appropriate level of consistency and product safety¹⁹; and
- Creating avenues for public complaints about product safety and for surveillance, and following up as appropriate.²⁰

The Directive calls for the EU Commission to participate in a network of member state authorities.²¹ The network’s goals are to share product safety information throughout the EU, establish joint product safety surveillance and testing projects, exchange expertise and best practices and cooperation in training activities, and improve cooperation as to the tracing, withdrawal and recall of dangerous products.²² Among the tools used within the EU to achieve these goals is the Rapid Information System Exchange (RAPEX), which allows for timely exchange of product

invited to comment as drafting progresses, thus affording the savvy product manufacturer a number of ways to provide scientific or technical input and help shape a final standard.

14. Directive 2001/95/EC. This measure applies to all consumer products marketed in the EU except to the extent that their safety is governed by sector legislation, *i.e.*, medicines and motor vehicles.

15. Art. 8(2).

16. Art. 6(2).

17. Art. 7.

18. Art. 8.

19. Art. 9.

20. Art. 9(2).

21. Art. 10.

22. Art. 10(2).

safety and product liability information between member states. When a member state adopts or recommends measures to prevent or restrict the marketing and use of a product due to a serious risk, the member state must immediately notify the European Commission of such initiatives through RAPEX, and this information is then passed by the Commission to other member states.²³ RAPEX is accessible to “applicant countries, third countries or international organizations, within the framework of agreements between the Community and those countries or international organizations, according to arrangements defined in these agreements”²⁴ (*See e.g.*, the agreement between the European Commission and the CPSC). In this way, product safety information is already being posted and passed among nations at broadband speeds.

The latest version of the Directive has clarified some principles and obligations, but fundamental issues that could interfere with the adoption of uniform standards remain. For example, while the Directive sets out factors to consider in determining whether a particular product is “safe,” questions still arise as to how the factors are to be interpreted and applied. This is especially true in light of differing approaches to product safety and cultural differences across EU member states. Notification requirements also raise questions in relation to exactly when risk notification is required and what entity must be notified. In the end, the Directive’s problems in achieving uniformity may be related to decentralized enforcement mechanisms and the varying expectations and regulations of member states.²⁵

There are groups, such as the Product Safety Enforcement Forum of Europe (PROSAFE), that are attempting to strengthen links across national borders. Established entirely by European enforcement officers, PROSAFE members use online resources to coordinate community-wide enforcement activities. Members also meet periodically to share information and expertise. A more informal network, known as the International Consumer Product Safety Caucus (ICPSC) provides another meeting point for regulators. Its objectives include developing cooperation arrangements to facilitate surveillance and enforcement for internationally-traded products; exchanging information on best practices for risk assessment, market surveillance and enforcement measures; and identifying common needs, priorities and guidelines for international standards. ICPSC members meet in conjunction with yearly U.S. and international meetings of the International Consumer Product Health and Safety Organization, which is a coalition of health and safety professionals from

23. Art. 12(1).

24. Art. 12(4).

25. Bernardino Muñiz, *Practical Aspects of the Product Safety Legislation*, Int’l L. Ofc., Nov. 16, 2006.

government, manufacturing, legal, testing and certification, SDO, media and consumer advocacy sectors.²⁶

Uniformity poses less of a problem in the United States because consumer product manufacturers, as a rule, have only one agency to notify of potential safety problems. A notification obligation in the EU must, in some circumstances, be directed to the relevant competent authority in each of the twenty-five member states where the product is marketed or otherwise supplied to consumers.²⁷ This would require facility with different languages, marketing channels, corrective action mechanisms, and individual regulatory approaches among national authorities. In those member states divided into autonomous regions, notification of product risk may also have to be given to the competent authority of each region.

A duty to notify is triggered under different circumstances in the United States and the EU. In the United States, action must be taken when “information reasonably supports the conclusion” that the product falls into one of several defined categories. Immediate notification means that the information must be provided within twenty-four hours, if it is clearly reportable. If not clearly reportable, the reporting company may conduct an investigation for up to ten days. In the EU, a duty to notify appears to arise “immediately” and in any event within ten days, whether or not an investigation has been completed. A product posing a “serious risk” must also be reported immediately, and in any event within three days; a risk rising to the level of an “emergency” must be reported by the fastest means available.

INTERNATIONAL REGULATORY MECHANISMS—THE ROLE OF SDOs

The International Organization for Standardization (ISO) is an organization with the potential to bridge product safety differences between nations. In recent years, ISO has begun to pay more attention to consumer products and has developed a new family of standards on toy safety.²⁸ ISO established a Consumer Policy Committee that has called for

26. When the International Consumer Product Health and Safety Organization met in Bethesda, Maryland, in May 2006, participants agreed to a “Bethesda Declaration” expressing shared values and steps to implement those values. Available at <http://www.icphso.org/AnnualMeeting/FinalBethesdaDeclaration.pdf>. The organization’s third meeting and training symposium in Europe was held in Brussels, November 29-30, 2006. During this symposium, European regulators were slated to present their plans and priorities for future collaboration, and the United States and Japan were expected to sign an agreement on guidelines for cooperation on consumer product safety. See Meeting Information, ICPHSO, available at http://www.icphso.org/EuroMeet_1.html.

27. Directive Annex 1 and Guidelines for the Notification of Dangerous Consumer Products to the Competent Authorities of the Member States by Producers in Accordance with Article 5(3) of Directive 2001/95/EC. Discussions are ongoing within the Health and Consumer Protection Directorate of the European Commission in connection with development of a Web-based notification system.

28. See International Organization for Standardization, *Safe Toys for the Children of the World: A Crucial International Standard for Manufacturers and Authorities in All Countries*, ISO

the development of an international standard that would provide guidance on how to identify, assess and eliminate or reduce risks associated with consumer products generally. The committee has also proposed the adoption of an international standard on the establishment, implementation and management of a consumer product recall program.²⁹

ISO's focus on the harmonization of consumer safety standards is important for at least two reasons. First, under World Trade Organization (WTO) rules, national standards must be based on international standards if they exist. ISO is the premier organization issuing international standards on which national standards are based. Second, ISO cooperates with SDOs in the development of national voluntary standards. The American National Standards Institute (ANSI) is the U.S. representative at the ISO table.³⁰

A Case in Point—Pictograms: Faced with dozens of languages by which to provide product warnings in global markets, product manufacturers have been working with organizations such as ISO to develop universal symbols to convey safety information. A quick glance at a product as commonplace as a laptop computer's AC adapter readily shows how such initiatives are already having cross-border effects. Manufactured in China and sold in the United States, a typical adapter has a label with several pictograms warning of electrical shock (a triangle with a jagged vertical line ending in an arrow) and explaining the product's usage (a house silhouette with an arrow pointing to its interior). ISO Technical Committee 145 is actively developing standards to universalize the symbols used in safety signs and warnings. Fifteen nations have actively participated in this effort, with another thirty-one nations participating as observers.³¹ As a result, the committee's work product is being implemented worldwide.³² It is worthwhile to note, however, that pictograms cannot be

BULLETIN, March 2000, at 4, available at <http://www.iso.org/iso/en/commcentre/pdf/Safetoyo0003.pdf>.

29. Press Release, American National Standards Institute, ISO COPOLCO Calls for Measures to Enhance Consumer Product Safety (June 7, 2006), available at http://www.ansi.org/news_publications/news-story.aspx?menuid=7&articleid=1245.

30. ANSI adopted a *United States Standards Strategy* at the end of 2005 that sets forth several goals with an international focus, including: (i) "actively promote the consistent worldwide application of internationally recognized principles in the development of standards," (ii) "work to prevent standards and their application from becoming technical trade barriers to U.S. products and services," and (iii) "strengthen international outreach programs to promote understanding of how voluntary, consensus-based, market-driven sectoral standards can benefit businesses, consumers and society as a whole." ANSI, *United States Standards Strategy passim* (2005)

31. Geoffrey Peckham, Chair, U.S. ANSI TAG to ISO/TC 145, *New Signs: The Key to Communicating Safety in Buildings*, ARCHI-TECH, May-June 2006.

32. ISO Standard 3864-1 sets rules for the color and shape of safety signage. Thus, warning signs consisting of a yellow triangle with a black outer band, containing a black graphical symbol, provide hazard warnings. A prohibition, on the other hand, is depicted as a circle surrounded in red with a red slash from top left to bottom right over a black graphical symbol.

viewed as a panacea for the problem of providing consistent warnings across multiple languages due to inevitable variations in interpretation. Nevertheless, they are emerging as one useful tool in the international provision of warnings information.

PRODUCT STANDARDS AND THE DUTY OF CARE

In addition to the financial and logistical burden of complying with different safety regulations, requirements or standards in different countries, many consumer product manufacturers are concerned that such differing compliance will create ammunition for product liability litigants who could claim that the reasonable alternative design available in another country was not available in their country. The allegation will be that the failure to incorporate the “foreign” product feature renders the product defective or such failure constitutes negligence on the manufacturer’s part. The difference between the U.S. and foreign product design features may simply be the result of mandatory and competing regulatory regimes. Fortunately, U.S. courts *generally* do not allow the introduction of international designs, warnings or standards in products liability cases.³³ Still, this risk may be reduced or eliminated for manufacturers that sell products worldwide through the globalization of product safety standards.

We note, however, in the interest of being thorough, that evidence of U.S. domestic industry or other voluntary standards is permitted in more than a few U.S. jurisdictions by either plaintiffs or defendants.³⁴ Compliance or non-compliance with standards may provide at least some evidence as to whether the product was defective (in the case of strict liability) or whether the defendant was negligent.

CONCLUSION AND RECOMMENDATIONS

Enhanced international communications about product safety, product safety standards and regulatory schemes are beginning to benefit consumers to the extent that product safety information is becoming more readily available and disseminated globally. Yet, manufacturers, distributors and others in the commercial stream are facing regulatory compliance and product liability concerns that cross borders in ways not previously envisioned. Clearly, the internationalization and harmonization of

33. See, e.g., *Deviner v. Electrolux Motor, A.B.*, 844 F.2d 769, 773-74 (11th Cir. 1988) (affirming district court’s exclusion of Swedish safety standards for chainsaws to avoid juror confusion); *Garmon v. Cincinnati, Inc.*, 1993 WL 190923, *2-3 (Tenn. Ct. App. June 4, 1993) (finding no abuse of discretion to exclude evidence of English product safety standards, because “rules and standards not having the force and effect of law are not admissible as evidence.”).

34. See, e.g., *DiCarlo v. Keller Ladders, Inc.*, 211 F.3d 465, 468 (8th Cir. 2000) (allowing defendant to introduce evidence that ladder from which plaintiff fell complied with ANSI standards); *Moulton v. Rival Co.*, 116 F.3d 22, 26 (1st Cir. 1997) (allowing admission of evidence that potpourri pot probably did not meet relevant safety standards).

product safety standards will continue, and this trend will have an impact on the development of products liability litigation in the United States and elsewhere around the globe, as courts take compliance with product safety standards into account when making decisions about product defects or manufacturer liability. With new challenges, however, come new opportunities. By establishing best manufacturing practices, monitoring applicable standards development activities and taking action to influence standards development in a way that provides a measure of control over the future business environment, a consumer product manufacturer will be well situated to compete in the global marketplace.

Certainly, in one light, consumer product safety harmonization initiatives can be viewed by manufacturers as a serious threat—one complaint in one country concerning one product can travel the world and have regulatory and, perhaps, liability implications in “virtual” time. To the extent, however, that “one world/one product” is a strategic objective for any manufacturer, the harmonization of product safety standards may well present substantial opportunity. Clearly, it is not economical to develop products to meet the different regulatory requirements of every country. As ISO would have it, “one standard, one test” for products can minimize the costs associated with research and development, design, manufacturing, labeling, and sale of products such that the harmonization of standards would benefit any company exporting products for sale in the global marketplace. The benefits would be more significant for multi-national companies that research, develop, manufacture, assemble and sell products globally. Moreover, manufacturers benefit to the extent that harmonization: (1) results in fewer non-tariff-based impediments to trade and (2) potentially, reduces litigation and related expenses. Consumers also benefit from such a harmonization through better products which carry better information at a price that reflects the economies introduced by harmonization.

Based on the foregoing, our recommendation is that whether or not manufacturers elect to embrace the globalization of product safety systems and standards, they should recognize the need to actively participate in the process. Some companies may wish to simply monitor the development of standards and other regulatory developments – this much is essential. More so, we would strongly recommend that manufacturers consider finding more direct ways to participate in the process—by joining or actively working with SDO committees, participating in the ISO Technical Committees (of which there are more than 225) or otherwise engaging in the standards development and harmonization process. Doing so can only improve the quality of the regulatory schemes and provisions that will be applied to consumer products. Opportunities for participation can be identified when the CPSC publishes notices in the *Federal Register* about its meetings and rule-making activities. Similarly, ISO’s Web site can be reviewed for opportunities to actively participate in initiatives of the technical committees that develop standards. The same is true for

other SDOs such as Underwriters Laboratories, to name just one of the more than 200 SDOs accredited by ANSI. It will take time and effort to actively participate in these standards development activities or to stake out a position in the international arena. The payoff, however, is the potential for the development of one uniform international standard and, thereby, one uniform product for the global marketplace that furthers a manufacturer's desire for a level playing field in the marketplace and in the courtroom, both locally and globally.