So You Want To Enter the U.S. Market: Twelve Simple Steps to Avoid Litigation



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It is well known that U.S. consumers have a tremendous appetite for Asian designed and manufactured goods. Even in a depressed economy, consumers still seek out and will pay a premium for the quality and style offered by Asian companies, which cannot be duplicated anywhere.

However, many companies are hesitant to enter the U.S. market due to our complex legal system and the risk of litigation. They are correct to be concerned. American society is very litigious. The U.S. litigation rules seem incomprehensible and counter intuitive. A lawsuit is a very expensive and time consuming process. The U.S. court system is very consumer oriented, and American juries do not hesitate to render jury verdicts in the millions of dollars. These factors are enough to dampen the enthusiasm of any business wishing to enter this lucrative market.

However, all is not lost. The minefield of potential litigation can be safely navigated with the help of an experienced litigator: one who can provide preventative strategies focused on helping your business avoid or reduce the attendant risks. Surprisingly, these risks can be avoided for a nominal cost. A company simply needs to become aware of the various risks, and then implement policies and procedures to address them. If it is later sued, these policies and procedures will enable the company to present a formidable defense, thereby considerably reducing its exposure.

Below is a twelve-step system for keeping your business on track, and out of the U.S. courts, as you enter the U.S. marketplace. Planning must begin *now*, before you enter the market, so you are as protected as much as possible from the time of your first sale. Even if you are already in the U.S. market, it is never too late to implement these procedures and minimize future risk.

1. Confirm there are no potential patent, trademark or other intellectual property violations

Brand recognition is considered by many to be the single most important asset of a company. Consequently, you will be spending a tremendous amount of time, money and energy developing your brand in the U.S. However, are you free to use your company name or product name, or even sell your product, in the United States?

I have been hired to assist several clients who had entered the U.S. market with great fanfare, advertising their company name and product name in media blitzes throughout the U.S. However, after spending *a lot* of money, my clients received letters from another company claiming that the other company was already using my clients' company name and/or product name, or a confusingly similar name. The other companies demanded that my clients immediately "cease and desist" from any future use of my clients' cherished name.

Similarly, I have seen numerous situations in which the "unique" designs offered by my clients were, in fact, covered by the patent or other intellectual property rights of another company. Therefore, according to the law, my clients were not permitted to make, use, or sell their own products in the United States! The other companies also sent my clients cease-and-desist letters, demanding that my clients refrain from profiting from the market they themselves developed.

In these situations, my clients had four choices:

1. Withdraw from the United States market, and waste all of the time, money, energy and other company resources invested. Of course, no one wants to make this presentation to the CEO.

- 2. Change the company name, or the name of the product, that my clients already spent a great deal of resources developing. Alternatively, the design of the product may need to be modified to avoid the other patent. However, the costs associated with the simplest change on 1,000 units of a product, especially after they have already been imported and distributed, could be crippling.
- 3. Ignore the cease-and-desist letter and follow the original marketing plan, hoping that the other company does not have the resources to pursue a lawsuit, or, if a lawsuit is started, that its claim can be defeated. However, intellectual property litigation is a *very* expensive proposition and the legal fees and expenses reach the *millions* of dollars range. Therefore, even if you win, you have lost. Further, a cease-and-desist letter transforms your company from an "innocent infringer" to a "willful infringer," thereby exposing your company to triple damages and payment of the other side's attorney's fees (in addition to your own attorney's fees).
- 4. Negotiate a license with the other company. However, if the other company is in a strong legal position, it will be unreasonable and will drain all of the profit from your Unites States activities.

Therefore, failure to confirm the restrictions that may exist in the United States market can place you in an extremely uncomfortable position, with no attractive option to escape. My clients in the above situations were dumbfounded when they learned that truly minimal effort would have been necessary to avoid these tremendous and expensive problems. Do not fall into the same trap.

2. Protect your own intellectual property

If your company name, product name or logo has strong market recognition, you must protect it. If your product offers a "new, useful and non-obvious" design feature, you must prevent others from stealing your design. If your product incorporates other trade secrets, methods of doing business, confidential business plans, or other intellectual property, you must have the necessary non-disclosure agreements and contracts in place to prevent third parties from unfairly profiting from them.

Without the proper protections, established from the start, a third party could steal the fruit of your research and development, product planning, marketing strategies, and other hard work, pushing you out of the very market you created. The costs to protect your intellectual property would pale in comparison to the potentially staggering losses.

3. Confirm the product complies with relevant standards

The United States has numerous federal, state, municipal and local standards which affect the design, manufacture, sale, use or labeling of your product. Some of these standards are "mandatory" and others are "voluntary." A short list of some of the bodies which promulgate standards is:

- 1. American National Standards Institute (ANSI)
- 2. American Society of Testing and Materials (ASTM)
- 3. Underwriters Laboratories (UL)
- 4. National Highway Traffic and Safety Administration (NHTSA)
- 5. Consumer Products Safety Commission (CPSC)
- 6. Food and Drug Administration (FDA)
- 7. Federal Trade Commission (FTC)
- 8. United States Coast Guard (USCG)
- 9. Federal Aviation Administration (FAA)
- 10. Snell Memorial Foundation
- 11. ...and many others

The terms "voluntary" and "mandatory" can lead to confusion for a company and therefore expose it to risk. A mandatory standard is one which *must* be complied with in order for a company to be permitted to sell its products in the United States. Compliance with a voluntary standard is within the discretion of the manufacturer.

However, from a litigation perspective, *all* standards are mandatory. If any aspect of a product — its design, method of manufacture, raw materials, product literature, or product labeling — does not comply with a mandatory or voluntary standard, then that product can be deemed defective, and it will expose the company to litigation and the payment of damages. If the non-compliance with the standard is deemed intentional, you could be exposed to punitive damages.

Often, a product can be brought into compliance with the relevant standard with minor modification. However, redesigning a product, re-printing its packaging, re-purchasing the raw materials, or otherwise making any change is usually cost-prohibitive after the fact. Nominal research is required to identify, understand and comply with the relevant "voluntary" and "mandatory" standards to foster a smooth and profitable entry into the U.S. market.

4. Confirm that owner's manuals, warnings, instructions and warranties comply with standards and the law

In my 21 years of representing product manufacturers, during which I have handled hundreds of product liability matters, I have seen just two products that were truly defective in manufacture. While almost all plaintiffs allege that a product is defective in design, in most cases we were able to develop formidable defenses to the plaintiffs' claims, supporting the design of the product and eviscerating the plaintiffs' claims. The reason? Companies spend millions of Euros designing their products. They spend millions more in developing state-of-the-art manufacturing facilities. These cases are much easier to defend.

However, in most of the cases I have handled, the plaintiffs also claimed that the warnings, instructions and other product documents (such as the owner's manual, warranty and advertising literature) did not comply with the relevant standards and law. Unfortunately, in many of these cases, the plaintiffs were correct, thereby exposing my client to significant risk. The reason? In their rush to bring the products to the market, the companies did not spend adequate time in developing the owner's manuals, the on-product warnings and other literature. Even if they did prepare some literature, they did not follow the relevant standards and law governing the form and content of this information. The most perfectly designed and manufactured product will still be found to be defective if it does not adequately warn of the risks associated with its use, and otherwise comply with the relevant requirements.

The amount of time required to develop the appropriate product literature, and the associated costs, is infinitesimal in comparison to the costs associated with the design, engineering and manufacture of the product. Further, the cost savings associated with avoiding a "failure to warn" claim are incalculable. Quite bluntly, I am baffled by the poorquality literature that accompanies the high-end products developed by some manufacturers, and greatly concerned by the tremendous risks presented. This is one of the easiest risks to eliminate.

5. Confirm that advertising literature and other product labeling complies with applicable statutes controlling product representations

Many states have enacted various "consumer protection" or "commercial fraud" statutes which affect the representations made by companies in their advertising campaigns. Further, similar laws control the representations that can be made on the product itself (e.g., under what circumstances may you stamp on the product "Made in Italy" when its component parts come from or are assembled in China?).

Additional regulations strictly control the ingredients you may use in your products and the disclosures which need to be made about these ingredients. Cosmetics, for example, are highly regulated by the government, requiring full disclosure about potential adverse reactions. Likewise, there are strict limits on the amount of lead which can be in your products. These laws also provide that if they are violated, any consumer injured (either physically or financially) as a result of the violation can sue, recover triple damages, as well as attorney's fees.

A company must fully evaluate and comply with the controlling law and regulations before investing time, money and energy in its advertising campaigns and product labeling.

6. Develop document retention systems

In a products liability lawsuit, a company is obliged to present evidence to refute plaintiff's claims that the product is defective in design, manufacture or warnings. As a part of this proof, the company must produce documentation regarding:

- a. Research and development
- b. Design calculations
- c. Testing
- d. Manufacturing
- e. Quality control
- f. Warranty claims
- g. Advertising
- h. Accident / failure / complaint /claims history
- i. Market research and analysis

This documentation is critical to a company's ability to demonstrate the great care invested in each product when bringing it to market, along with its superior design attributes.

When this documentation is not available, the plaintiffs' attorneys invariably claim that the company destroyed its records for a sinister purpose, such as to conceal evidence that is prejudicial to its defense. I have read many judicial decisions in which a company was sanctioned (sometimes severely) by the court for its inability to produce documents or to satisfactory explain their unavailability.

Claims are usually brought many years after a product is designed, manufactured or sold, after engineers or records custodians have retired, warehouses are moved, divisions are bought and sold, and other changes have occurred within the company. Consequently, companies are often unable to locate the documents that are critical to its defense.

Companies must have in place – *today* – appropriate document and data retention systems which define the categories of documents which can be destroyed (if at all) and when they can be destroyed. Further, the system must properly identify, catalog, maintain and store those categories of documents which must be retained in anticipation of future product liability claims. A properly prepared, implemented and utilized system will enable companies to present the strongest possible defenses to plaintiffs' claims, prevent negative inferences by plaintiffs' attorneys, and avoid sanctions by the court.

7. Develop warranty and product surveillance procedures

A company must closely follow the performance of its products in the field and immediately react to any potential hazards that may be presented to consumers. In addition, today's society no longer permits a company to simply monitor the performance of their own products. They are obliged to follow the use, misuse and accident trends in the entire industry which could affect the safety of its products. Companies are then obliged to react to *any* situations which could present a hazard to the consuming public.

Consequently, a company must have in place the appropriate product and market monitoring systems, and well-defined procedures which will govern how the company will react to a potential safety issue. The company must properly document its reaction, or reasons for non-reaction. Failure to do so could cast the company in an unfavorable light before an unsympathetic jury.

These systems and procedures are not difficult to implement; in fact, they are often a corollary to a company's usual marketing activity. Therefore, for little to no additional costs, a company can secure a great deal of protection.

8. Develop electronic discovery management programs

Check your sent box to see the number of emails you sent just today. Multiply that by the number of employees in your company. Estimate the number of recipients who then forwarded those emails to others, and further multiply by the number of servers each email passed through to reach their recipients. Further compound this for each day of the year for the past five years. The number of emails sent by your company's employees is staggering.

In a lawsuit, a plaintiff will demand production of *all* emails relating to a particular topic. You are obliged to search for and produce those emails. Could you find an email you sent four years ago to one of your colleagues on a particular topic? If your company does not have an electronic discovery protocol in place, a great deal of time, money and energy could be lost in trying to locate this email. More likely than not, you will not be able to find it.

If the email is not located, the plaintiff can secure a court order preventing your company from backing up its electronic data. Depending on the size of your company, the failure to back up your data can overload your computer system, causing it to crash in a matter of minutes.

Next, the plaintiff could secure a court order granting his expert full and unrestricted access your individual desktop computers and servers, company wide, to search for that email. The plaintiff will also request that you pay his expert's costs. The expert will then have access to *all* of your confidential data.

Finally, document management programs are mandated by law in certain circumstances. The court can also impose penalties for failure to have a system in place.

The potential risks associated with not having an electronic document management system tremendously outweigh the nominal costs to develop one.

9. Use your website wisely

Your website is the single most efficient method to communicate with your customers. You can provide them with real-time information regarding the use of your products. You can make available owners manuals and other critical safety information. You can provide them with historical information regarding prior recalls. You can publish your policies and procedures with regard to your commercial relationships (for example, you can publish your warranties and purchase order terms). Finally, you can provide your customers with an avenue to provide you with critical market information which you would not otherwise learn yourself.

You already have a website. There is no reason not to fully exploit its full potential to protect yourself. Properly developed and managed, your website can help you avoid litigation, or give you a tremendous advantage if a lawsuit is started. Your company is already investing resources to develop a website; invest just a bit more to maximize its value to you.

10. Procure the appropriate insurance

No business can operate without insurance. However, insurance is very expensive. What type of insurance do you need, and how much should you buy?

I have had a number of clients purchase unnecessary insurance at enormous cost. For example, the U.S. subsidiary of a foreign manufacturer which distributes the manufacturer's products may not need to procure its own product liability insurance.

Before you buy any insurance, you should consult with a broker who is skilled in international markets and an attorney who can help identify the insurance you really need. The tremendous savings can be re-invested in your business.

11. Develop effective agreements

Each commercial relationship, like every marriage, is entered into with the hope and expectation that it will be mutually beneficial and without conflict for years to come. Experience has taught us all that this is not always the case. Therefore, with each commercial relationship, you must hope for the best but plan for the worst.

All of the agreements you prepare must have a common aim: insulate your company from liability, and/or transfer the risk of litigation to another party. At a minimum, your company must develop the correct distribution agreements, indemnity agreements, purchase order terms, and terms and conditions of sale.

Each agreement must include the appropriate risk-shifting provisions and indemnity clauses. Furthermore, your agreements must include the necessary acknowledgements regarding ownership and non-infringement of your intellectual property, non-disclosure of your trade secrets, confidentiality agreements, and limited licenses. In addition, in anticipation of litigation, you need to include the necessary choice of law, arbitration (if desired) and venue provisions.

Most companies know that contracts are necessary and try to prepare some sort of agreement. Spend a little more time to do everything possible to make them as complete as possible. Just like in any divorce, failure to plan is often met with a great deal of regret.

12. Have a recall plan

Despite the greatest of product designs, despite the most advanced engineering and reliable manufacturing facilities, despite all reasonable care, things can go wrong. When this happens, a company must be prepared to act decisively, quickly and effectively. It needs a recall plan.

There have been numerous instances in which a company was punished for not conducting an effective recall. This punishment can take different forms. Initially, punishment can come from a governmental regulatory agency, such as the Consumer Products Safety Commission (CPSC) in the form of significant fines, penalties and other sanctions. For example, failure to comply with the CPSC regulations could result in fines of up to \$15,000,000.00.

Next, a plaintiff's attorney can put your product on trial and try to establish the "wanton and reckless disregard for the rights and safety of others" in order to support an award of punitive damages.

Finally, there is the court of public opinion, which can tarnish the reputation of your company and all of its products. Years of hard work in developing a strong market presence can be erased overnight. You may recall the problems faced by Audi in the 1980s which nearly caused it to declare bankruptcy, and the recent costs to Toyota to rehabilitate itself after the "sudden acceleration" allegations.

Your company must have in place the proper systems to monitor product performance in the field, procedures to identify and evaluate potential issues, and measures to quickly and effectively react. United States consumers and its regulatory agencies do not tolerate anything less.

13. Insure that your employees can work for you

We have gone beyond twelve steps, but this is one additional point that must be considered here, even though it is not related to litigation. Your business model may be dependent on a few key employees of your company. Without them, your venture can fail. Can they obtain a visa to enter the United States?

The U.S. immigration laws set forth very precise and uncompromising requirements before a foreign person may enter the U.S. to work. Many companies are surprised at how difficult it can be to obtain a visa. Therefore, pre-planning and evaluation is key.

Identify the people you will need to make your business a success, and then contact an immigration attorney to make sure they will be able to enter the United States to perform their jobs.

Conclusion

You are already working very hard to enter the U.S. market, and hopefully you will be very successful in your endeavors. Spend a bit of extra effort to make sure your success is not impeded due to a *preventable* problem.

Frank J. Ciano is a partner in the U.S. law firm Goldberg Segalla LLP. He has extensive experience representing international corporations in products liability, commercial, corporate, regulatory and intellectual property litigation. He focuses his practice on assisting his clients in avoiding the risk of litigation and, in particular, minimizing their exposure to products liability claims and commercial litigation. http://www.qoldbergsegalla.com/attorneys/frank-j-ciano