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A. Facts and Scope of Review

If a manufacturer wants to sell its products to customers in the US, it will often sell its products to a wholly-owned Delaware limited liability company (“Subsidiary”) and the Subsidiary will sell the products to customers in the US. This memo will summarize the key risks a manufacturer is exposed to from such sales as the manufacturer and distributor of the products and parent of the Subsidiary.

This memo will not discuss the tax impact from such sales or corporate structure or any liability arising from the non-compliance with environmental standards or infringement of third party’s intellectual property rights.

B. Summary

In the event that any of the products that a manufacturer manufactures or distributes cause bodily injury or property damage, the manufacturer can be held liable under the laws of all 50 US states even if it sells such products through a Subsidiary (see Section C.I.). Complying with the recommendations under Section C.I.2. will help to minimize the manufacturer’s risk exposure. Product liability suits may, however, incur significant legal expenditures for a manufacturer even if the outcome is in the manufacturer’s favor. It is therefore advisable to purchase sufficient insurance coverage for product liability suits and related legal costs.

A manufacturer can reduce its liability exposure with respect to most claims not based on product liability, e.g. warranty claims, by marketing its products to customers in the US through a Subsidiary. To ensure that US courts respect the liability protection provided under state laws to members of a limited liability company, the Subsidiary must be operated as a distinct business (see Section C.II.). Both the manufacturer with respect to sales to the Subsidiary and the Subsidiary with respect to sales within the US should try to minimize their risks contractually (see Section C.III.). Such limitations will only apply to the contract parties but may entitle the manufacturer and Subsidiary to indemnification and being held harmless and may protect them from being dragged into a product liability suit aimed against another party in the distribution chain.

C. Legal Considerations

It is essential to understand that product liability, contract and corporate law are governed by the laws and courts of the individual US states and that each jurisdiction has its own set of rules and judicial precedents. A comprehensive illustration of all issues involved would therefore be a monumental undertaking. It is feasible, however, to summarize the key aspects that most jurisdictions consider critical. The following will address and summarize these key aspects. Due to its nature of an overview, this illustration is not comprehensive and further legal counsel may be required when particular questions and issues arise.

I. Product Liability

State product liability laws provide customers with a direct claim against anyone in the distribution chain, including the manufacturer, distributor and seller of a defective product.

1. Liability of Manufacturers, Distributors and Sellers

Under the laws of all 50 states, manufacturers, distributors and sellers are directly liable to customers for harm to persons or property caused by defective products. A product is deemed defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. Liability can also arise from misrepresentations, post-sale failures to warn or recall products.

The liability of the manufacturers, distributors and sellers for harm to persons cannot be reduced contractually. Disclaimers and limitations of remedies and other contractual exculpations that a Subsidiary may negotiate with its customers will not bar or reduce an otherwise valid products liability claim by the injured person against the manufacturer or Subsidiary.

2. Recommendations

A manufacturer can take steps during the design and manufacturing process and after the sale of a product, which may prevent a suit from being filed or, at the very least, will enhance the manufacturer’s chances of defeating a lawsuit if filed. To avoid or defeat a lawsuit, the manufacturer must be able to demonstrate that its product was reasonably safe for its intended use, that it was adequately tested, and that it was accompanied by appropriate warnings. The following steps can assist a manufacturer in making such a demonstration.

3. Design Process

It is critical to understand that the recognized engineering principles related to product design are in a hierarchical form which requires all hazards to be identified at the development stage. With respect to each hazard, the design engineer must determine whether the hazard can be designed out. If the hazard cannot be designed out, the engineer must determine whether the hazard can be guarded against. Only
as a last resort if the hazard cannot be guarded against, the hazard must be **warned about**.

A manufacturer will have a strong defense against the allegation that its product is defective if it rigorously complies with and documents the following design and testing process:

- constantly evaluate and examine the design of the product to insure that it is safe for its intended and foreseeable use;
- evaluate the potential misuses of the product (*e.g.*, what might the end user of the product do with the product that was not intended by the manufacturer); the manufacturer should take steps to prevent any foreseeable misuses (*e.g.*, by warning about the dangers of such misuse);
- evaluate the probability of injury/damage and severity of harm;
- make certain that the product’s safety devices are "state of the art," and be prepared to improve those safety devices as technology changes and advances;
- determine what, if any, governmental and industry standards apply to the product (voluntary or mandatory) and make certain that the design and manufacture of the product meets or exceeds all such standards;
- thoroughly test the product before sale (*e.g.*, test to assure compliance with standards and regulations; test all likely failure modes);
- consider a periodic "safety audit" of the product, performed either by the company’s own engineers and safety personnel (perhaps a "safety committee") or by outside consultants.

4. **Warnings and Product Materials**

If a product can cause injury or property damage under circumstances during its intended or foreseeable use, and the risk of injury cannot be eliminated (*e.g.*, by designing it out or guarding it out), then the product must be accompanied by appropriate warnings. The warnings and manuals will be a significant element of the manufacturer’s defense:

- warnings should reach the intended and foreseeable users of the product (*e.g.*, if they appear on a label, they should be visible and placed where they are not likely to be removed or covered up);
- warnings and product literature should identify the hazard and how to avoid it and warn of the precise risks involved with the product;
- warnings and product literature should comply with all applicable regulations (*e.g.*, American National Standard for Product Safety Signs and Labels (“ANSI”) Z535).

5. **Document the Design and Manufacturing Process**

A manufacturer needs to follow and document a rigorous product development and testing process. Demonstrating the reasons for the design decisions and the hazard analysis process will be critical to the defense of the product. Yet, a manufacturer must take care that documents are not created casually and
without thought or, more importantly, leaving critical issues unanswered. Employees should be encouraged to follow these general guidelines:

- write accurately and factually; avoid opinions, speculation, and exaggeration; communicate only what needs to be said (e.g., jokes and humor can often be misinterpreted particularly by lawyers);
- if a document creates an open issue, particularly one concerning safety (e.g., notice of a safer alternative), that "loop" must be closed and the closure should be carefully documented;
- internal memos and correspondence are inappropriate forums to wage turf battles; employees should avoid blaming others for mistakes or failings through internal memos;
- to the extent possible, sensitive documents should be reviewed by counsel before dissemination and/or should be directed to counsel (corporate or outside) to attempt to protect the confidential nature of the communication;
- all advertising literature, brochures, operating manuals and instructions should be carefully reviewed by all appropriate persons (e.g., marketing, engineering and legal departments);
- the company should establish a document control and retention policy; remember: a manufacturer will need documentation to demonstrate its design and manufacturing process; these documents should be kept in an orderly manner and for an appropriate period of time.

These are just some of the steps that can be taken to minimize the risk of product liability litigation. There are many others (e.g., establishing a product safety program for handling and reviewing complaints concerning products and alleged injuries). A manufacturer that is proactive concerning safety will fare much better in avoiding lawsuits and defeating them if filed.

6. **Shift the Liability**

For any supplies or materials that a manufacturer purchases for its products and for other products and parts supplied by third parties, the manufacturer should attempt to contractually shift the liability to such suppliers. This is typically done through defense and indemnification clauses with upstream distributors and manufacturers.

7. **Insurance Coverage**

Even if complying with the recommendations set forth above, it is advisable to obtain sufficient insurance coverage for product liability claims and related legal expenditures. The insurer should preferably be located within the US so that claimants have no temptation to seek a deep pocket abroad.

8. **Regulatory Agencies**
The US government has various agencies that regulate the design, manufacturing, labeling, distribution, and transportation of products. Different regulations may apply depending on the type of product that a manufacturer manufactures or distributes. The following non-exhaustive list provides examples of US agencies with regulations that may apply to the manufacturing or distribution of products:

- The US Food and Drug Administration ("FDA") regulates the safety and labeling of food products, drugs, vaccines, blood products, medical devices, cosmetics, veterinary products, and tobacco products.
- The US Department of Agriculture ("USDA") regulates livestock meat and poultry products.
- The US Department of Transportation ("DOT") consists of multiple regulatory agencies that regulate the transportation of products, materials, and passengers by road, rail, air, and sea.
- The US Environmental Protection Agency ("EPA") enforces laws and issues regulations related to emissions, pollution, toxic waste disposal, nuclear waste, and other environmental concerns.
- The US Consumer Products Safety Commission ("CPSC") regulates the safety of consumer products.

II. Parent Liability for Other Claims

Obligations arising under product liability may not be the only liabilities that a manufacturer or Subsidiary might incur when selling to customers in the US. Other liabilities, based on contract, in particular for breach of warranties, or tort can also be substantial. A manufacturer will typically not be liable for such claims if it is not involved in the sales by the Subsidiary to its customers.

A manufacturer may, however, be held responsible for the liabilities of the Subsidiary if the manufacturer’s relationship with the Subsidiary qualifies for the so-called ‘piercing the corporate veil’ doctrine. The term ‘corporate veil’ refers to the liability limitation that is afforded to shareholders of a corporation and members of a limited liability company ("LLC"). The following will first discuss the standards that courts and commentators apply to corporations and, subsequently, what this means for the Subsidiary.

1. Alter Ego or Instrumentality

As a general rule, two separate corporations are regarded as distinct legal entities even if the stock of one is owned wholly or partly by the other. There is a presumption of separateness that a claimant must overcome to establish liability of a parent company by showing that (i) the parent is employing the subsidiary to perpetrate a fraud or commit wrongdoing, (ii) the subsidiary is so controlled as to be the alter ego or mere instrumentality of the parent and (iii) that this was the proximate cause of the claimant’s injury. All jurisdictions recognize some variation of these standards and, although the standards are not always identical, require a showing of substantial domination.

2. Wholly Owned Subsidiaries
Courts apply particular scrutiny when the corporation is owned by a single shareholder. The evaluation of corporate control claims cannot, however, disregard the fact that, no different from other stockholders, a parent corporation is expected - indeed, required – to exert some control over its subsidiary. Limited liability is the rule, not the exception. There is no single factor that alone justifies disregarding such limited liability, i.e., piercing the corporate veil. Instead, the totality of circumstances and relationship between the corporate entities and their directors and officers must be evaluated.

3. Liability Without Fraud

If a parent’s exercise of dominion and control over its subsidiary defeats the payment of its just obligations, courts do not necessarily require a showing of fraud. In addition, many jurisdictions that require a showing of fraud, injustice, or inequity in a contract case do not in a tort situation. A rational distinction can be drawn: In actions based on contract, the creditor has willingly transacted business with the subsidiary although it could have insisted on assurances that would make the parent also responsible. In a tort situation, however, the injured party had no such choice; the limitations on corporate liability were, from its standpoint, fortuitous and non-consensual.

4. Piercing the LLC Veil

There has been an explosive surge in the growth and popularity of the LLC starting in the 1990s. Nonetheless, there is still relatively little LLC veil-piercing case law. To complicate the matter, not all jurisdictions have LLC acts that specifically address these questions. Furthermore, because many of the organizational formalities applicable to corporations do not apply to LLCs, in the absence of a statute, it is unclear what factors would justify piercing an LLC veil. As more LLCs are becoming involved in litigation, there have been a number of decisions that address these questions. Courts in leading cases have substantially applied the standards that would be applied if the subsidiary was a corporation. Furthermore, most commentators have predicted that courts will apply some form of the classical corporate veil-piercing doctrine to LLCs. It is likely, however, that the doctrine will be modified to account for the differences between corporations and LLCs, in particular considering that, generally speaking, LLCs do not have to abide by many of the formalities required of corporations.

5. Agency Problem for Involvement in Negotiations

A manufacturer could also be held liable for the Subsidiary’s acts if the manufacturer dominates the activities of the Subsidiary as to establish an agency relationship. Generally, for this to occur, this control must be actual, participatory, and total. A manufacturer may also be liable under an agency theory if there is active and direct participation by a representative(s) of the manufacturer, apparently exercising some form of pervasive control, in the activities of the Subsidiary, and there is some fraudulent or injurious consequence of the intercorporate relationship. In general, however, if a manufacturer exercises control at a board level and allows US managers to run the US business, this is considered quite normal and would
rebut a claim that the manufacturer is “dominating” the Subsidiary to such an extent that it should be held liable for whatever the Subsidiary does.

6. Recommendations

To determine the likelihood that a court in an action brought by a creditor of the Subsidiary would pierce its veil and hold the manufacturer directly liable, the following questions need to be answered:

- Do the manufacturer and Subsidiary have different directors or officers?
- Do the manufacturer and Subsidiary have separate business departments?
- Do the manufacturer and Subsidiary file separate financial statements and tax returns?
- Does the Subsidiary have its own bank accounts and finance itself?
- Does the Subsidiary operate with adequate capital?
- Does the Subsidiary pay its salaries and other expenses?
- Does the Subsidiary’s business go beyond the business given to it by the manufacturer?
- Does only the Subsidiary use its property as its own?
- Are the daily operations of the manufacturer and Subsidiary kept separate?
- Does the Subsidiary observe the basic formalities, such as keeping separate books and records and holding shareholder and board meetings?

The very nature of these often very difficult issues makes their resolution extremely fact dependent. In most situations, none of these factors alone justifies piercing the corporate veil. On the other hand, having to negate most or all of these questions makes it very likely that a court will disregard the separateness of the Subsidiary.

7. Personal Jurisdiction over Parent

Special problems are presented by service of process on a Subsidiary as a way of asserting jurisdiction over an out-of-state parent. When a Subsidiary of a foreign corporation is carrying on business in a particular jurisdiction, the parent company is not automatically subject to jurisdiction in that state because of the presumption of corporate separateness. Thus, if the Subsidiary’s presence in the state is primarily for the purpose of carrying on its own business and the Subsidiary has preserved some semblance of independence from the parent and is not acting as merely one of its departments, personal jurisdiction over the parent corporation may not be acquired simply on the basis of the local activities of the Subsidiary. On the other hand, if the Subsidiary is merely an agent through which the parent company conducts business in a particular jurisdiction or its separate corporate status is formal only and without any semblance of individual identity, then the Subsidiary’s business will be viewed as that of the parent and the latter will be said to be doing business in the jurisdiction through the Subsidiary for purposes of
asserting personal jurisdiction.

III. Contractual Strategy
For a manufacturer’s sales to the Subsidiary and for the Subsidiary’s sales to another company in the distribution chain, the manufacturer and the Subsidiary should (try to) stipulate contractual terms that will minimize their risks. Typically, a component supplier can demand that the customer indemnifies for (i.e., pay claims) and holds it harmless from (i.e., pay legal costs) claims and costs that may be incurred in defending a product liability claim. In addition, the companies could consider inserting a dispute resolution clause into customer agreements that requires arbitration, or litigation in a friendly and convenient US jurisdiction. This does not prevent an injured party from claiming against the manufacturer or the Subsidiary, but may prevent the customer (if sued) from dragging the manufacturer or the Subsidiary into a lawsuit where the injured party has sued the customer that assembled and delivered the final product.

This strategy needs to consider, though, that sometimes the most knowledgeable person should be responsible for defending a product liability claim under a cost-sharing agreement with the involved insurance companies and others in the distribution chain. This would avoid a downstream distributor who does not have the knowledge or expertise from attempting to defend it on its own with poor results that would encourage a flood of litigation.