

What Irish and Northern Irish Companies Need to Know Now: Selling to the U.S. Market

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Why Do Irish and Northern Irish Companies Need This Webinar?

- The U.S. market should be at the top of every Irish and Northern Irish company's expansion list:
 - Common language (although we have accents);
 - Large and active consumer market (we like to buy lots of 'stuff');
 - Affinity for Irish and Northern Irish products; and
 - Similar economic and legal systems.
- Reputation may suggest that the U.S. market is 'risky' or 'difficult,' but the reality is different.
- Keep in mind, though, that certain kinds of business activities (even online sales) could put those activities by an Irish or Northern Irish company under the jurisdiction of U.S. Federal or State law.

Why Do Irish and Northern Irish Companies Need This Webinar?

- Don't panic. With practical advance planning and understanding of potential risk points, the operational risk of exporting/expanding to the U.S. can be controlled and mitigated.
- We call this advance planning “smart exporting.” Exporting grows revenue and profit, but smart exporting can help your company perform even better.
- Trust us, we're lawyers.

Control the Contract

- In the U.S., as in Ireland and Northern Ireland, interactions between companies, and with consumers, give rise to a contract.
- That contract can be unwritten or implied through a course of dealing or it can be a written, explicit (but no cursing) document.
- As with most business operations issues, setting out in a written document the expectations, obligations, and rights of each party is preferable to asking a court to define those issues in the first instance.
- The most important way to mitigate risk is to consistently use “American-style” terms and conditions/agreements that you develop.

Terms and Conditions Wishlist

- These terms and conditions or agreements can mean hard-copy printed items as well as the terms that can be posted and used online.
- Such terms should be regarded as a minimum baseline for exporting/expanding to the U.S., and can be augmented by Service Agreements, Distribution Agreements, and other business agreements (provided that the terms are referenced in or appended to the 'larger' agreement).
- You should be clear that there is no agreement or contract unless and until final approval of both sides is secured.

Terms and Conditions Wishlist (cont'd)

- Terms and Conditions/Agreements should include:
 - Choice of law and choice of forum;
 - Payment terms and consequences for late or non-payment;
 - Limitations of liability;
 - Disclaimer of certain warranties;
 - Dispute resolution provisions;
 - Amendment and waiver restrictions;
 - IP reservations;
 - Shipment terms;
 - Indemnification; and
 - Termination language.
- A key point is that these kinds of Terms and Conditions/Agreements should be used on a consistent basis.

Securing Payment

- Few things are worse than selling to a customer 3,000 miles away in another country, and then getting stiffed on payment.
- Consider multiple payment options:
 - Payment before shipment and use of credit cards;
 - Using letters of credit;
 - Requiring a deposit;
 - Using guarantees; and/or
 - 30/60 day terms.

Securing Payment (cont'd)

- Your terms and conditions should state that:
 - Late payment may be subject to an interest charge;
 - Late or non-payment may result in termination or suspension of future or outstanding orders;
 - Late payments could alter the 'usual' payment terms by, for example, allowing you to ask for a letter of credit or guarantee;
 - Non-payment or consistent late payment can result in termination of, for example, a distribution agreement; and
 - In the event that you have to sue to recover overdue amounts and are successful, the customer agrees to pay all of your expenses (not just legal fees) in connection with that collection effort.

Effective Use of Terms and Conditions of Sale

- **Specify shipment terms:**
 - Defines when title and risk of loss passes from you to the customer
 - Most common reference is to the shipment terms in INCOTERMS 2013
 - But be specific with the reference to INCOTERMS, since certain U.S. terms differ from their INCOTERMS counterparts
- **United Nations Convention on the International Sale of Goods**
 - Does not automatically apply to sales from Ireland or Northern Ireland to the U.S., since neither Ireland nor the U.K. have ratified the convention
 - Nonetheless, if you don't want it to apply, specifically disclaim applicability in the Terms/Agreement

Effective Use of Terms and Conditions of Sale (cont'd)

- **Protect your IP**
 - The Terms/Agreement should specify that any and all IP in your products remains with you, and that no grant of IP is made by the terms and you should restrict customer's use of your IP;
 - Obligate customer to not modify or otherwise change your IP;
 - Any TM or copyright markings should not be obscured or modified;
 - Be expansive in considering what IP you're using—there are differences between the IP in a product and the IP in a user's manual, for example;
 - Consider what IP filings you may want or need to make in the US, either directly or through a multilateral mechanism; and
 - Consider a separate license agreement.

Products Liability: Key Principles

- U.S. products liability is the set of cases and laws establishing legal responsibility:
 - of a product's seller or manufacturer
 - for harm to person or property
 - from a product defect.

- Tort claims based on not only theories of negligence but, in many cases, strict liability

What Types of Product Claims Exist?

General categories of claims include:

- Manufacturing defect: Was there a flaw in the way the particular product was made?

- Design defect: A risk-utility balancing. Could an available and reasonably cost-effective alternative have avoided or prevented the injury?

- Improper/insufficient labeling. Could appropriate instructions or warnings have avoided or prevented the injury?

- Breach of warranty: Inaccuracy of a claim, express or implied, about the product

Minimizing Products Liability Risk for the Ireland/Northern Ireland Company

- Management should develop, in advance and in tandem with counsel, a risk avoidance strategy that includes both legal and operational elements, including
 - Appropriate manufacturing quality control; testing; inspection; and recall and retrofit procedures
 - Thorough recordkeeping and document retention
 - Consistent and complete contracts
 - Review with counsel of labeling and instructions and advertising/marketing materials
 - Appropriate corporate affiliate or distributorship structure, considering U.S. jurisdictional issues
 - Crisis management team and action plan in place

U.S. Customs/Import Regulations

- Each product imported into the U.S. passes through US Customs.
- There may be limitations or bans on the import of certain products, or duties payable on specific goods.
 - IP infringement-related import bans.
- Certain INCOTERMS shift the responsibility of customs clearance to a purchaser.
- In many situations, the purchaser would be regarded as the 'importer of record' and have first-line responsibility for customs compliance.

Insulating the Parent, Its Assets, and Its Investors

- Irish or Northern Irish company may be concerned that a plaintiff may seek to use U.S. courts to reach the company, its assets and/or investors. This concern can be mitigated.
 - The Irish/Northern Irish company could protect itself by conducting all U.S. sales through an independent distributor.
 - The Irish/Northern Irish company could form a U.S. subsidiary (Delaware C corporation, generally) as a ‘blocker,’ so long as the parent does not encourage the subsidiary to target promotion to specific jurisdictions...be sure to observe corporate formalities.
 - Beware of the single entity concept and the risks of agency.
 - Maintain appropriate insurance.
 - Websites?

Life Sciences

- FDA regulates items that are in the commerce of the United States, regardless of their origin.
- FDA regulates items such as drugs (Rx and OTC), medical devices, biologics, food (including dietary supplements), cosmetics, and tobacco products.
 - Items that may not “seem” regulated by FDA (but are): sunscreen, multi-vitamins, surgical gloves and gowns, and skin creams.
- What other items could be regulated by US FDA?: mobile apps that track a patient’s health, and energy drinks or foods marketed with certain claims.

Life Sciences (cont'd)

- **Getting to (and Staying on) Market:**
 - Approval – Required for any “new” drugs (New drug application or abbreviated NDA); Premarket Approval Application for certain types of devices; biologics obtain licensure.
 - Clearance – Required for certain (and most) medical devices (510(k) application).
 - Establishment Registration – Required for drug, device, dietary supplement, and food facilities; voluntary for cosmetic facilities.
 - Miscellaneous Requirements – e.g., product listing for drugs and medical devices, quality related standards, such as Good Manufacturing Practices, post-marketing issues (e.g., advertising and promotion, corrective actions).

Life Sciences (cont'd)

- **Business Considerations for Irish and Northern Irish Life Sciences Companies:**
 - The party registered with FDA as the owner of the NDA, ANDA, PMA, or 510(k) is the party with ultimate regulatory responsibility (whether located in the U.S. or not).
 - All parties registered with FDA are subject to compliance enforcement (e.g., distributors, packagers, labelers, contract manufacturers).
 - While a U.S. distributor may handle the marketing and labeling of a product in compliance with FDA regulations, the Irish/Northern Irish manufacturer would still be subject to FDA scrutiny. If FDA had concerns about the product, they could place an import hold or inspect the manufacturer.

Healthcare

- Irish/Northern Irish life sciences companies may manufacture items that could be reimbursed by Medicare or Medicaid, with certain additional compliance obligations:
 - The federal anti-kickback statute impacts certain business practices when selling products reimbursed by Medicare or Medicaid, or used in procedures that are reimbursed, regardless of the nationality of the selling company. Irish/Northern Irish companies selling reimbursable products are subject to the anti-kickback law. Note that the law allows for criminal sanctions and for exclusion from reimbursement.

Healthcare (cont'd)

- Sales representatives interacting with US-licensed physicians must follow certain ethical guidelines and publically disclose marketing expenditures (e.g., meals with customers must be modest and the amount spent on the meal is publically disclosed on a government website).
- The anti-kickback statute requires transparency in pricing and discounting when selling to US customers, and the federal and state governments can demand access to sales contracts, invoices and other materials to confirm pricing.
- Reimbursement status is driven by Center for Medicare and Medicaid Services and the state Medicaid programs, and involves formulary placement negotiations and lobbying for coverage under existing or new codes.

US Federal Government Contracts

- As you can tell by the US Federal deficit, the U.S. government likes buying 'stuff.'
- In some areas, the government is a significant purchaser.
- Irish and Northern Irish companies may sell to the US government—one way is to get on a GSA schedule.
- Purchasing decisions made based on a combination of price and product quality—a best value calculation.
- Be aware of the pros and cons of contract set-asides.
- Seek out prime contractors.
- Many IT contracts are sole-sourced.

Software Licensing

- In addition to the items included under our discussion of Terms/Agreements, those accessing the U.S. market through licensing arrangements should be sure that the license includes:
 - The format in which the software will be made available;
 - Usage restrictions;
 - An appropriate definition of 'results' and ownership/use thereof;
 - Confidentiality requirements;
- Understand that technology (including software, know-how, techniques, and processes) can differ from IP, at least for licensing purposes; copyright and trade secrets

Software Licensing

- Licenses can be limited by geography, time, seats, customers and specific products/applications.
- Can be exclusive or non-exclusive.
- Related maintenance or support?
- Beware of “work made for hire” rules.
- Open-source issues and notice requirements.

Some Business Suggestions

- Consider regional differences in the U.S. market, and don't look at the U.S. market as unitary or homogenous.
 - Could seek to break in to a few regions first (such as the Northeast, Mid-Atlantic, or Southeast) before expanding.
- If you're thinking about a partner, do some thorough due diligence.
- Plan, including deciding on corporate structure, insurance, and other risk-avoidance measures
- Differentiate your product/service from others.
- Exclusive arrangements not always advantageous.

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