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Marine Transportation Becomes Feasible for Pharmaceuticals

Marine Transportation Becomes Feasible for Pharmaceuticals from AIR to OCEAN

Low Costs, Fail-safe Temperature Control, 24-7 Visibility Are Attractive

Ocean shipping has long been the transportation mode of choice for low cost goods with long shelf lives. Items that were high value, high tech or had limited shelf lives were shipped air cargo or, once on the continent, by truck or train. That is beginning to change. Now, even pharmaceutical manufacturers and logistics providers are exploring ocean shipping for all or part of a journey.

The use of ocean shipping for pharmaceuticals isn't yet commonplace, and it isn't without risks, but some of the world's largest pharmaceutical companies are looking seriously at options and are testing some routes. Their willingness to consider an alternative to air cargo is based upon three things: declining profit margins triggered by the impending patent cliff, when many blockbuster drugs will go off patent; increased globalization that is opening remote, often developing, markets; and improvements in temperature control and monitoring capabilities.

Low Cost Transportation Needed

To put all that in perspective, by 2018, some $17 billion of branded pharmaceutical products will lose patent protection. Those revenues won't be replaced by other blockbuster drugs, but with many drugs with smaller revenues and greater expenses.

Those drugs, increasingly, require controlled temperatures. The current market for pharmaceutical cold chain (2°- 8°C) logistics is valued at $7.5 billion in 2013 and is expected to reach $9.3 billion in 2017, according to the 2013 Biopharma Cold Chain Sourcebook. Additionally, controlled room temperature (CRT) – defined as 15°C and 25°C – is becoming more important. Respondents to a Pharma IQ survey reported that 63 percent are investing in CRT shipping solutions, and 50 percent said at least half their products require CRT storage.

Regulators throughout the world are watching the growth of temperature-sensitive pharmaceuticals and are increasing their scrutiny. There is no single, global standard for good distribution practices. Instead countries craft their own, with slight variations and are expanding their attention from the cold chain to include controlled temperature concerns.

Much of that growth in cold chain and CRT pharmaceuticals is in emerging regions. For example, while the U.S. cold chain logistics market is projected to grow slightly more than 20 percent by 2017, to $3.09 billion, the Asian market is expected to grow nearly 67 percent to $2.58 billion, surpassing Europe.

As the supply chain lengthens, margin pressures are increasing. Consequently, pharmaceutical shippers are looking for transportation options to lower the costs of air shipping, the traditional transportation mode. Some, according to logistics providers, are quietly exploring marine transportation.

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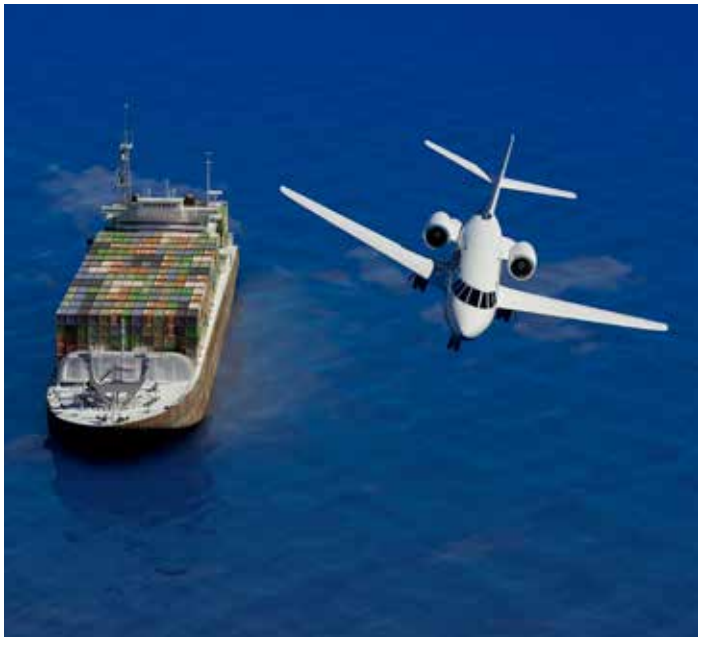

Intermodal

In late 2012, some of the world's major pharmaceutical companies teamed with two innovative pharmaceutical logistics providers to pilot intermodal transportation for less urgent shipments. The intermodal options combine air, road, and – innovatively – ocean freight and will operate on two continents. Cargo temperatures will be monitored throughout transit.

For pharmaceuticals, the inclusion of water-based transportation for even a part of the journey is revolutionary.When shippers think of intermodal transportation, they typically first think of planes and trucks, but "intermodal" means the combination of multiple modes. For example, cargo may be air-freighted to Singapore and barged to destinations along the coasts of Malaysia and Indonesia before being trucked inland. This provides a low-cost alternative for product arrivals that are not time-critical. Pharmaceutical logistics providers suggest that a significant portion of pharmaceutical shipments could be accomplished using ocean transportation.

Because many pharmaceutical shipments cannot fill a 20 or 40 foot reefer, pharmaceutical logistics providers are exploring options to lower transportation costs by cooperating with competitors to ship goods with similar requirements. Consolidation has been used successfully in other industries for less than truckload shipping, and holds promise for pharmaceuticals, as well.

Considerations

Low costs are the obvious advantages of ocean shipping. Typically, ocean cargo is shipped for 80 to 90 percent less than the same cargo could be air shipped. That's a compelling incentive, but other factors must also be considered.

Transoceanic transit times are measured in weeks rather than hours. For example, rather than two day air cargo, ocean freight leaving North America may take 35 to 40 days to reach India, China or other distant markets. Because that extra time increases the carrying costs for the product, transoceanic transportation may be reserved for lower cost, bulkier products with long, stable shelf lives. Increased transit time may be offset by enhanced

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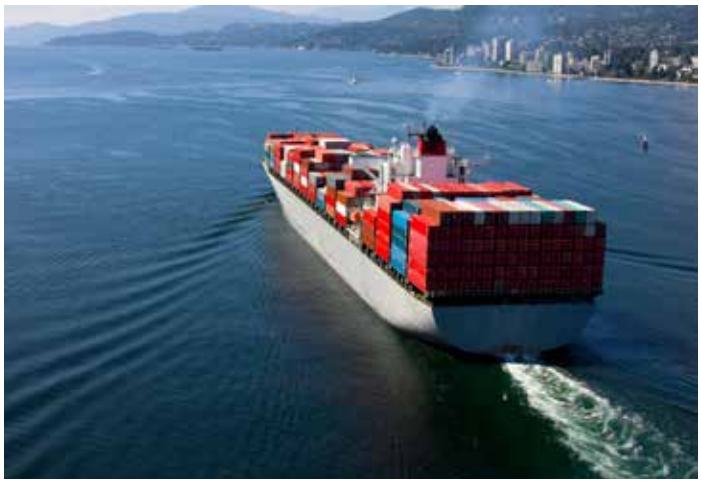

security. Refrigerated containers – reefers – are packed and sealed and, once loaded onboard ship, generally cannot be opened until they are unloaded at their destinations. Therefore, the entire transit can be made without risk of pilferage.

Available in 20 and 40 foot sizes, a generator in the reefer's nose contain circulates conditioned air, maintaining frozen, cool and controlled room temperatures throughout the journey. Special reefers can keep products frozen at temperatures as low as -60°C, though others can maintain the 2° to 8°C common for pharmaceuticals, or the 15° to 25°C increasingly used for CRT shipments. The most advanced reefers now offer digital temperature controls that provide a high degree of precision. Some containers also control atmospheric pressure and humidity.

Some new reefer designs also offer dual refrigeration systems. The backup system is activated if power is lost for any reason, including loading and unloading, or if refrigeration equipment malfunctions. Such systems ensure that proper temperatures are always maintained.

Advances in remote monitoring technology offer another safeguard. By monitoring temperatures inside the reefers 24/7, wireless data monitors can provide a continual view into the environmental conditions the products are experiencing. Reports meeting the stringent standards of the FDA's 21CFR part 11, the PDA 1079 and other good distribution and chain of custody guidelines may be issues daily, weekly, or monthly. This constant monitoring provides accurate, objective proof of conditions and is accepted by the U.S. courts in product liability cases.

The potential danger with ocean shipping is that if something does go wrong, remediation may not be easy or, sometimes, possible. The container in question may be stacked tightly or high in the shipment, making it inaccessible for days or weeks. Shipping lines recognize this problem. Some, like Maersk, now monitor reefers round the clock, placing reefer consultants on board and at the terminals to prevent or resolve issues before they escalate and endanger cargo.

No shipping method is completely safe from the potential for failure. Air cargo, for example, relies upon active containers and, often, upon passive solutions systems that depend upon insulation, refrigerants, or vaporized liquid nitrogen. Active systems still depend upon an external power source. Passive option, typically used for pallet and smaller sized shipments, can maintain temperature for several hours with refrigerants or for several days with liquid nitrogen vapor systems. If, however, flights are delayed or diverted, or if customs clearance is slow, personnel on the ground may need to take actions to prevent or minimize product loss.

Process Development

Container validation is another concern in a highly regulated industry. In a manufacturing environment, specific equipment may be validated. In shipping, however, a class of equipment or packaging may only be qualified. This is done by a series of steps that includes component qualification, operational qualification and performance qualification. Combined, these steps assure that the shipping container is capable of its task, performs well at operational extremes and performs well under real-world conditions.

New shipping options also require pharmaceutical shippers to update their standard operating procedures to account for these changes. For example, procedures must be developed to ensure temperatures are maintained throughout transit, and to be able to adjust temperatures if deviations occur.

Lengthened transit timeframes also must be accounted for, not just in terms of product shelf live, but in terms of when product must be ordered and shipped. Shippers should also ensure that ports of entry have the needed facilities and expertise to handle pharmaceutical shipments.

Logistics providers can address many of these issues. For example, logistics organizations are beginning to test and document conditions during shipping and, in some cases, are championing innovative options and technologies to make shipping safer and more efficient for their clients' products.

Ocean shipping is become feasible for pharmaceuticals, for at least part of the journey. Intermodal options are beginning to consider marine transport as a low-cost solution for stable products that have the luxury of longer delivery times. And, new technologies, including roundthe-clock remote monitoring systems, are providing the additional safeguards needed to provide the visibility and documentation needed to support stringent, regulated, pharmaceutical good distribution practices throughout the world.