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Innovations in APIs - Quality may give edge

DR SANJAY AGRAWAL

Introduction

APIs or Active Pharmaceutical Ingredients are the active ingredients present in drugs. It is believed that synthetic APIs market will be one of the leading industries in the years to come. The demand for higher quality and lower cost ingredients combined with tremen-

surpassing the North American market and the United States markets. India is the second-largest supplier of generic APIs to the US market with around 30 per cent share.

At present, there are less than 2,000 API manufacturing companies in India and China. Of the suppliers, the leading API manufacturers in India are (GSK) GlaxoSmithKline,



dously growing demand for complex molecules and the generics throughout the supply chain is completely reforming the API industry.

Current Status

The Indian market of APIs is taking a new turn and is expected to cross a revenue of nearly US\$6 billion by the end of 2020. Mainly the Indian APIs market manufacturing segment is dependent on two sectors 1) branded and 2) generic or unbranded.

Until recently the API market was dominated by the US followed by China which is now considered as a leading producer of APIs. China is considered to be the largest producer of APIs, accounting for almost 50 per cent of the global market

Aurobindo Pharma, Teva Active Pharmaceutical Ingredients (TAPI), Dr Reddy's Laboratories, Pfizer and so on.

Rise of API Market in India Patent Expiry

The patent expiry of many blockbuster drugs that is an ongoing process and is believed to be one of the major cause to further contribute to the growth of the API market in India. The major market for APIs in India is concentrated around the synthetic API market than for the biotechnology market for a long time till now. The increase of the biotechnology sector in India has caused an increase in biotech API market as well, but still this market continues to lag behind the synthetic API market.

CONTINUED ON P 92 ►



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CONTINUED FROM P 91 ►

Need for Complex Molecules

The demand for micronised APIs, drugs delivered using specialised delivery systems and polymers as well as painkillers formulated have all forced for the innovation and specialisation in the sector. The most important trend today we see in the global API market is increased focus on complex formulations in generics as a part of development. This is mainly because among patient populations, all those with chronic diseases and those requiring treatments in oncology, immunotherapies, and respiratory, for example. These are supposed to be one of the very complex conditions that are demanding a wide range of complex treatments using complex molecules.

Generic Focus

The drugs that are mainly in the pipeline for the APIs are the once whose patent is off patent or soon-to-be off patent.

Quality Concerns

Reports suggest that most of the APIs that are being used worldwide are manufactured in China, which is being widely acknowledged as the largest supplier globally. This is seen as a problem by observers and market analysts, who state that there are repeated and ongoing regulatory concerns and red flags about API manufacturing standards of China making it as a major concern.

The recent issue with tainted Valsartan that was produced in China is a case in point. This has enlightened the path for many manufac-

turing companies to start API manufacturing instead of acquiring APIs from other companies. They have expanded their capabilities and started manufacturing APIs.

Environment Concerns

The other pivotal issue that has changed the dynamics of the API market sector in recent years is that number of studies have linked improperly treated wastewater discharge

The drugs that are mainly in the pipeline for the APIs are the once whose patent is off patent or soon-to-be off

from drug ingredients product facilities. Therefore various efforts to encourage manufacturers to source from API firms that process wastewater appropriately had to be introduced, only companies that are encouraging green were in favour for the regulatory. Likewise, individual pharmaceutical companies in India have taken it as a point of importance and have taken steps like in case of GSK, J&J, Merck, AZ, Pfizer and others committing to reviewing their practices.

Future Trends

The Indian pharmaceutical industry ranks one among the top API markets in the world and China is its major competitor. The lower cost of the manpower and the growing tech-

nology and innovation are some of the main factors supporting its growth.

The API industries in India include those that are for domestic consumption as well as exports. API manufacturers of India are trying to strengthen their global marketing by different means mainly by focussing on the improvement of production of especially complex products as stated above, by thorough process modification, by increasing strategies to increase sales in international market and so on.

The Indian companies manufacturing APIs are being obliged to the standards and are compliant with many international regulations. Also the improvements in the field of technology in the country have enabled many manufacturers to venture into the highly regulated markets of the countries and regions like the United States and Europe.

This has led to Indian APIs getting approvals in various countries, increasing therapeutic applications and manufacturing facilities and henceforth aggressively strengthening credibility in regulated markets.

These API companies, are continuing to outpace the Chinese, Italian and other competitors in terms of DMFs, which are seen as a gradient of quality. Higher quality of the ingredient, coupled with cost-effectiveness has made India increasingly attractive for API outsourcing in the recent times.

In fact, India has been recognised as one of the leading global players with the filing of large number of DMFs and dossier registrations for APIs, with several manufacturing facilities approved by the regulatory authorities of developed countries.

Conclusion

The important players being China and India are driving the market growth through their cost-effectiveness and regulatory or quality issues and have emerged as manufacturing hubs for APIs. But in the near future with government support, improving IP systems and manufacturing standards in India, it is expected that India will grow steadily in the coming years. In the near future, India may beat China in global APIs market. ○

(The author is a leading pharmaceutical consultant)

