Term 4 Intensive Revision

**Case Study Practice – Cost of Production, Market Structure**

**United States’ Pharmaceutical Industry**

**Extract 1: The Pharmaceutical and Biotech Industries in the United States**

The United States is the world leader in biopharmaceutical research and development (R&D). In particular, San Francisco Bay Area and Northern California have the largest concentration of biotech companies in the nation. It is home to nearly 1,377 life science and biotech companies that employ more than 140,000 people. Bioscience companies based in the Bay Area reported total worldwide revenues of $4.1 billion and exports worth $2.7 billion.

The largest aggregation of research universities and federal research institutions in the U.S. is also in the Bay Area. “We are located in Emeryville, Calif. to leverage the rich intellectual talent in the San Francisco Bay Area, collaborating with academic institutions and biotechnology companies to improve patient outcomes.” said Mariellen Gallagher, a spokesperson for Novartis Institutes for BioMedical Research, the drug discovery unit for Novartis.

According to the Pharmaceutical Research and Manufacturers Association (PhRMA), U.S. firms conduct the majority of the world's research and development in pharmaceuticals and hold the intellectual property rights on most new medicines. Its strengths include an intellectual property system that rewards innovation through patent and data protection, a science-based regulatory system that is considered the most rigorous in the world, the world’s largest scientific research base fostered by academic institutions and decades of government research funding, and robust capital markets.

Source: *SelectUSA*, accessed 10August 2017

**Figure 1: Projected total worldwide Pharmaceutical Research and Development (R&D) Spending from 2016 to 2022**

Source: *EvaluatePharma*, accessed 10 August 2017

**Extract 2: Patent in the U.S. Pharmaceutical Industry**

The policy debates in the pharmaceutical industry revolve around promoting innovation and increasing competition in markets. The level of R&D in the industry relies heavily on the patent system. The firm which developed the drug are rewarded from monopoly profits of the drug sales for the duration of the patent. Discovery of new drugs confer benefits to the society with more effective and improved health outcomes. On the other hand, once the patent expires, the entry of generic drugs manufacturers erodes patent-protected monopoly profits and reduces the associated society’s deadweight losses. Although the patent on an innovative drug expires on a specific date, the drug's trademark may live on and possibly delaying or impeding subsequent competition.

Because regulation and patents has had important effects on the level of innovation in the pharmaceutical industry, a great deal of research has been done on this trade-off between innovation and competition.

Source: *Harvard University and National Bureau of Economic Research,* accessed 10 August 2017

**Extract 3: Competition from generic drug producers**

Generic medicines are proven to be chemically and therapeutically equivalent to originator brands, but are significantly cheaper. Generic drug manufacturers do not incur R&D costs and are able to offer a significant price advantage to the originator brand. The use of generic medicines has been seen in many countries as a partial remedy to address the problem of ever increasing expenditure on pharmaceuticals.

Falling drug prices can have a tangible impact on one’s treatments for illnesses that take a particularly large toll on the nation’s health. For example, the cost of high cholesterol medication [fell by 10 percent](http://www.reuters.com/article/2013/03/05/us-expressscripts-prices-idUSBRE92406W20130305) for a 30-day supply, which quickly reduces the healthcare spending for patients who have chronic conditions like excess cholesterol and diabetes.

Source: *LSE Health*, The London School of Economics and Political Science, accessed 10 August 2017

**Extract 4: India's Generic Drug Manufacturers: Poised for Continued Growth**

Over the last 10 years, the export prowess of India’s generic pharmaceutical industry has reshaped the global pharmaceutical business. Since the 1970s, with the abolition of patent protection rights, India’s pharmaceutical industry has been dominated by home-grown generic drug makers. Indian generic drug makers also managed to gain a foothold in regulated markets such as the US and Europe. In fact, Indian companies are second only to US-based companies in approval of generic drugs, maintaining a total share of nearly 30%-40% on a consistent basis.

Countries in the European and African regions are also the prime consumers for Indian generics medicines. Increasing influence of foreign multinationals has become a cause of concern for authorities and market players. At the same time, patent expiries may turn out to be a growth booster.

However, quality issues are an ongoing challenge for the Indian pharmaceutical industry. US Food and Drug Administration (FDA) has not only increased the frequency of its inspections but also intensified scrutiny on drug manufacturing facilities in India, resulting in delayed product approvals or restrictions in export to the US market.

Source: *Nasdaq*, 29 February 2016

**Extract 5: Is The Golden Era Of Pharmaceutical Profits Over?**

For decades, the pharmaceutical industry has been highly profitable. The recipe for such profits has been pretty simple for most of the last half-century – discover a chemical or molecule that treats a common problem, like hypertension or diabetes and make billions of dollars while that product is still under patent protection. But of course, profits were never so simple. It takes billions of dollars to develop one new drug suitable for testing in humans and even then, the drug might turn out to be too toxic or to have too little benefit to make it on to the market. It might take a handful of such drugs before a company finally finds one that works to recover the rising cost of new drug development. With the number of common illnesses in need of interventions dwindling and competition from generic manufacturers, it is getting increasingly difficult to earn enough to make up for the competition and cost of innovation.

Source: *Forbes*, 29 July 2016

**Questions**

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| **(a)** | In extract 1, it is mentioned that San Francisco Bay Area and Northern California have the largest concentration of biotech companies in the nation.  Explain how this might bring about cost savings to the biotech companies. [4] | |
| **(b)** | **(i)** | Describe the trend in projected total worldwide pharmaceutical R&D spending from 2016 to 2022. [2] |
|  | **(ii)** | Explain one reason for the trend observed above. [2] |
| **(c)** | Explain how the entry of generic drugs manufacturers after expiration of patent “reduces society’s deadweight losses” from monopoly pricing under patent. [4] | |
| **(d)** | Discuss the macroeconomic impact of the rise of India’s generic pharmaceutical industry on US and India. [8] | |
| **(e)** | The case study highlights various benefits and costs of the pharmaceutical industry to society.  Assess whether regulation through patent is the most appropriate form of government intervention in the pharmaceutical industry to maximise benefits to society. [10] | |
| [Total 30 marks] | | |
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