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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**Suggested Answers**

**(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]**

Biotech firms can benefit from reaping external EOS having the largest concentration of biotech companies in the nation.

**Economies of concentration**

As mentioned in extract 1, the 1,377 life science and biotech companies employs more than 140,000 people. This suggest a developed pool of skilled workers has been established in the region where the firms can leverage the rich intellectual talent in the San Francisco Bay Area. Firms benefit from lower search and recruitment cost of labour.

**Economies of information**

San Francisco’s Bay area and North California has the world’s largest scientific research base fostered by academic institutions and decades of government research funding. Firms can hence obtain up-to-date information on production at a lower cost by sharing the cost of research instead of spending on expensive research independently.

**(b)(i) Describe the trend in projected total worldwide pharmaceutical R&D spending from 2016 to 2022. [2]**

Projected total worldwide pharmaceutical R&D spending from 2016 to 2022 has been increasing at a rather constant rate.

OR

Projected total worldwide pharmaceutical R&D spending from 2016 to 2022 has been increasing at an increasing rate.

**(b)(ii) Explain one reason for the trend observed above. [2]**

The increase in projected R&D spending is due to lowered cost of R&D as evidenced in Extract 1 where there has been decades of government research funding which subsidises the firms’ research cost.

OR

An intellectual property system that rewards innovation through patent and data protection helps protect firms’ profits from sale of drug during patent period. This encourages firms to continue R&D in expectation of possible future profits with new drugs invented.

**(c) Explain how the entry of generic drugs manufacturers after expiration of patent “reduces society’s deadweight losses” from monopoly pricing under patent. [4]**

* Entry of drug manufacturers after expiration of patents increase number of firms in the market.
* Demand for firm (AR) decreases and become more price elastic.
* With the fall in price and quantity, mark up between P and MC is reduced.
* This reduces the DWL area. i.e society’s deadweight losses.

**(d) Discuss the macroeconomic impact of the rise of India’s generic pharmaceutical industry on US and India. [8]**

**Introduction**

Rise of India’s generic pharmaceutical industry has largely positive impact on India and negative impact on US.

**Main Body**

Positive impact on India

With reference to extract 4, Indian generic drug makers managed to gain a foothold in regulated markets such as the US and Europe, being second only to US-based companies in approval of generic drugs and with countries in the European and African regions also being its prime consumers. This indicates increase in X volume and hence revenue of India in generic drug exports. Also, investments in India’s pharmaceutical industry is likely to increase with prospering of the industry. Hence, AD increases as shown in figure 1 above, resulting in economic growth and improving BOP. More jobs are also likely to be created lowering cyclical unemployment.

Evaluation

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. To continue to export to the US market, firms in India has to ensure that they meet the stringent criteria and standards of FDA in drug quality.

Negative impact on US

As generic drug manufacturers in India do not incur R&D costs, they able to offer a significant price advantage to the originator drug brand of US firm. This suggests an increase in imports volume into US and hence import expenditure increases as patients switch to generic drugs as close substitutes since generic medicines are proven to be chemically and therapeutically equivalent to originator brands, evidenced in extract 3. Also, countries in the European and African regions are now prime consumers for India generics medicine as evidenced in extract 4. This suggests a fall in demand for US produced drug exports to these regions with the higher competition from India. X volume and hence revenue for US drug falls too. This worsens both AD and BOP of US, which may lead to higher unemployment rates.

Evaluation

Impact of competition is not only with US companies of brand drugs but also generic drug companies in US. Impact on macro goals could be more significant. However, being the world leader in biopharmaceutical research and development (R&D), with an intellectual property system that rewards innovation through patent and data protection, there is still room for US brand drugs companies to innovate on new drugs so as to capture sales and revenue in new drugs introduced. Investment level from the industry could still be high, hence mitigating impact on goals.

Also, introduction of generic drugs results in fall in drug prices. For example, in extract 3, fall in cost of high cholesterol medication quickly reduces healthcare spending for patients. This improves SOL for patients in US as savings from lowered drug price can be used to spend on consumption of other goods and services.

**Conclusion**

India likely to benefit from rise of India’s generic pharmaceutical industry as they expand to European and African regions beyond US. i.e less impact on stringent quality control of FDA and rapid expansion of markets

US on the other hand, is likely to suffer negative impact on goals as in extract 5, golden era of pharmaceutical profits are over. It takes billions of dollars to develop one new drug but too little benefit to make it on to the market. Brand drug companies in companies are likely to experience fall in profits and hence combining impact of competition from India, the industry might decline hence impact macro goals of US.

**(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]**

**Introduction**

Governments intervene in the pharmaceutical industry to achieve dynamic, productive and allocative efficiency. Due to the high degree of necessity of pharmaceutical drugs in curing some diseases, there are also equity issues that governments would like to address. Patents is one method that governments can implement to achieve these objectives and this can be compared to other policies that governments can implement to achieve the two goals of efficiency and equity.

**Main Body**

**Thesis 1: Regulation through patents is the most appropriate form of government intervention as it allows governments to achieve both dynamic efficiency.**

**Explain how patents allow protection of firm’s supernormal profits from innovation and provides incentive and ability to innovate.**

* Patents allow firm which developed the drug to be rewarded from monopoly profits of the drug sales during the patent period (extract 1)
* This suggests that demand for the drug will be highly price inelastic since no new firms rights to produce and sell the drug
* Draw monopoly diagram to illustrate supernormal profits
* The protected supernormal profits provides incentive and ability to firms to continue innovation in new drugs
* Dynamic efficiency is achieved, new drugs can cure and extend lives of patients 🡪 M and NMSOL can be improved

**Thesis 2: Patents balances effect of monopoly on drugs with improved efficiency once patents expires where generic drug manufacturers may now enter the market to sell generic versions of the drug.**

**Explain how patents with only limited period one expired allow entry of generic drugs manufacturers to erode patent protected monopoly profits and reduces the associated society’s DWL.**

* Possible to include diagram of fall in AR and gentler slope to indicate improved allocated efficiency
* The introduction of competition will help to improve productive efficiency of firms in the industry

Evaluation

It is difficult to determine the optimal length of the patent duration. If the patent expires too quickly, the firm that has developed the drug will not be able to reap enough profits to cover the cost of drug development. If the patent lasts too long, the firm reaps supernormal profits at the cost of consumer welfare.

**Anti-Thesis 1: Price regulation is a more appropriate form of government intervention as it allows governments to achieve allocative efficiency.**

* Oligopolistic market structure due to high barriers to entry and high fixed costs
* Demand for the pharmaceutical drugs highly price inelastic since few available substitutes
* Draw monopoly diagram to illustrate allocative inefficiency
* Furthermore, equity issue may result as low income households may not be able to afford expensive drug treatments
* Government may introduce AC or MC pricing to increase allocative efficiency
* P=MC, allocative efficiency is achieved

**Anti-Thesis 2: Reducing regulatory barriers to entry in the pharmaceutical industry is a more appropriate form of government intervention as it allows governments to achieve productive and allocative efficiency.**

**Explain how regulatory barriers to entry in the pharmaceutical industry may deter competition by new entrants. For example, the licensing process to get a new drug into the market is highly prohibitive (Extract 5: “billions of dollars to develop one new drug suitable for testing in humans”)**

* Thus, barriers to entry are very high hence, demand is highly price inelastic
* The incumbent firms in this oligopolistic market structure charge higher prices compared to the perfect competition equilibrium price
* P > MC 🡪 allocative inefficiency
* Reducing barriers to entry by simplifying the drug development process by reducing the time it takes to approve applications, making licensing fees cheaper, etc.
* Increase no of firms 🡪 reduce market share and power🡪 reduce allocative inefficiency and increase equity (lower supernormal profits)

Evaluation

However, there are other barriers to entry such as brand loyalty. This ensures that the barriers to entry in the pharmaceutical industry remain high. Furthermore, regulation exists to ensure that new drugs meet the necessary safety requirements. Other BTEs also include high start-up cost due to sophisticated machines required. Thus, governments can only do so much in terms of reducing regulatory barriers to entry. Might not improve allocative efficiency

**Conclusion**

Patents allow the government to balance the objectives of allocative and dynamic efficiency. It is appropriate because it is necessary for governments to protect intellectual property rights in order to ensure innovation. However, its limitation is in selecting the length of patent. Though reducing regulatory barriers may be a good strategy in theory, it is not appropriate to the pharmaceutical industry because there is a limit to how much the government can reduce regulatory barriers. Furthermore, it may be ineffective because the pharmaceutical industry already has numerous barriers to entry such as high fixed equipment costs or brand loyalty.