H2 Case Study 1 Answer

(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. Answer 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. 2m for each type of external EOS.	[4]
(b) (i)	Describe the trend in projected total worldwide pharmaceutical R&D spending from 2016 to 2022. Answer 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. 1 m for identifying increase 1m for constant rate of increase or increased rate	[2]
(ii)	Explain one reason for the trend observed above. 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	[2]

	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. 1m for stating the reason 1m for explanation	
(c)	Explain how the entry of generic drugs manufacturers after expiration of patent "reduces society's deadweight losses" from monopoly pricing under patent. Entry of drug manufacturers after expiration of patents increase number of firms in the market. [1] Demand for firm (AR) decreases and become more price elastic. [1] With the fall in price and quantity, mark up between P and MC is reduced. [1] This reduces the DWL area. i.e society's deadweight losses. [1]	[4]
(e)	Discuss the macroeconomic impact of the rise of India's generic pharmaceutical industry on US and India. Rise of India's generic pharmaceutical industry has largely positive impact on India and negative impact on US 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	[8]

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.

Level 2: Well explained analysis on both India and US considering internal and external macroeconomic impact. Max 4 for well-explained analysis of macroeconomic impact of either India or US or only internal or external macroeconomic impact.	4-6

Level 1: Under-developed analysis of macroeconomic impact on India and US.	1-3	
Evaluative Comment: Provide an evaluative comment and judgement on the overall impact on India and US economy	1-2	

(f) [10]

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.

Question approach: This question requires the student to compare the different ways governments might intervene in the pharmaceutical industry to increase consumer welfare by ensuring competitive outcomes, but still ensuring that producers have the incentive and ability to innovate.

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.

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.

Level 2: Well-developed explanation of how the policies allow the government to achieve its goals of efficiency and equity. Some credit will be given if students consider the impact of the policies on macroeconomic goals.	4-7
Level 1: Under-developed explanation of how the policies allow the government to achieve its goals of efficiency and equity.	1-3
E2: Provide judgement on the appropriateness of the policies with respect to the criteria of equity and efficiency.	2-3
E1: Evaluation without justification	1

[Total 30 marks]