II. Key features of innovation in the pharmaceutical industry

A. Huge and growing market

The world pharmaceutical market was estimated to be around 716 billion Euro at ex-factory prices in 2015. The bigest three markets in the world pharmaceutical markets are US, EU and Japan. The market share of these three regions are estimated to be around 48.7% (349 billion Euro) in the US, 22.2% (159 billion Euro) in EU and 8.1% (58 billion Euro) in Japan, respectively.[5] In addition to this market share, it should be noted that there is a rapid growth in the market and R&D environment in highly populated emerging markets such as Brazil, China and India. The Brazilian and Chinese markets grew by 14.0% and 7.0%, respectively. This growth is rapid, compared with an average market growth of 5.9% for the EU market and 8.5% for the US market.[6]

B. High R&D investment

The development of a new drug requires a substantial investment of capital, human resources, and technological expertise. Even if a pharmaceutical company successfully finds a promising candidate for a new drug, it has to tackle the next obstacles of strict adherence to regulations on testing and manufacturing standards before a new drug is used in real life. All these requirements become the factors to increase the cost of R&D for a new drug.[7] According to the survey in 2016, the cost of R&D for a new drug is estimated to be nealy 2 billion Euro.[8] This survey shows that the cost has been increasing since 1970 at the rate of becoming double in ten years.[9] The pharmaceutical industry is known as the sector with the highest ratio of R&D to net sales. The survey investigated the overall R&D

---

5 EFPIA, *supra* note 2, at 14.
6 EFPIA, *supra* note 2, at 4.
7 Dickson et al., *supra* note 4.
8 EFPIA, *supra* note 2, at 6.
9 EFPIA, *supra* note 2, at 9.

https://doi.org/10.5771/9783845294018-12, am 12.10.2024, 08:13:46
Open Access – (cc) BY - https://www.nomos-elibrary.de/agb

percentage of net sales in many industries[10] and found that the Pharmaceutical and Biotechnology sector ranks the highest with the percentage of 14.4%. It is followed by Software & Computer Services (10.1%) and Technology Hardware & Equipment (8.0%). And the average of all 41 industries is 3.4%.[11] This number clearly shows how outstanding the R&D cost in the pharmaceutical industry is.

One of the reason for this costly R&D mainly lies in increased regulatory requirements.[12] Before a pharmaceutical company puts a new drug on the market, it has to survive long and costly clinical trials. These clinical trials require more participants and longer period of trials than before because the trends in the type of new drug development have recently changed. It is also reported that recent R&Ds for new drugs are shifting to the treatment of chronic diseases, which needs a prolonged period of time for curement. Thus, the clinical trials would accordingly take a longer period to examine medical safety than drugs for other diseases. Therefore, for developing a new drug, one survey indicates that it would take an average 12.8 years currently, which shows significant increase from an average only 7.9 years in the 1960s.[13]

C. High Failure rates

One of the characteristic features in R&D for a new drug is very high failure rate. R&D for a new drug is roughly classified into two stages. The first one is the laboratory stage. The researchers try to examine many candidate chemical sibstances that they believe to be promissing. They usually obtain these substances by the extraction from naturally occuring products, the artificial organic synthesis or the combination of both methods. The process of extracting and synthesizing chemical substances takes a lot of investment, labor and time because the molecular structures of effective

10 Data relates to the top 2,500 companies with registered offices in the US (829), EU (608), Japan (360) and the rest of the world (703), ranked by total worldwide R&D investment (with R&D investment above 17.9 million EURO).

11 European Commission, EU R&D Scoreboard (The 2015 EU Industrial R&D Investment Scoreboard) 53, http://iri.jrc.ec.europa.eu/scoreboard15.html. The table 3.2 (Ranking of the top 11 industrial sectors by overall R&D in the 2015 Scoreboard.) shows these figures in the first column “Global R&D intensity (%)”.

12 Dickson et al., *supra* note 4.

13 Dickson et al., *supra* note 4.

https://doi.org/10.5771/9783845294018-12, am 12.10.2024, 08:13:46
Open Access – (cc) BY – https://www.nomos-elibrary.de/agb

drug components are nawadays so complex that it often includes many steps before final chemical substances are obtained. Then they conduct screening experiments using animals for all candidates in order to check characteristics including effectiveness and toxity. The successful rates for the candidates to survive the first stage is considered to be significantly low. If they are lucky enough to obtain good results, they will go on the second step; the clinical development, which is the experimental step involving human to check effectiveness and side effect on human body. There are several phases (Phase I, II and III) that should be passed until a pharmaceutical company finally obtains final approval. According to the survey in recent ten years,[14] the overall likelihood of approval from Phase I for all developmental candidates was reported to be only 9.6 %.[15] Chronic diseases are the hard category to obtain final approval with its overall likelihood of approval being 8.7 %.[16] For calculating total successful rates, it is necessary to multiply these two stages. It is reported that on the average only about one of every 10,000 (0.01%) chemical substances researched will successfully become a marketable drug,[17] and behind one successful project there are at least 9 unsuccessfull projects which nonetheless must have been financed.[18] Since a successful drug has to produce enough profit of R&D for next future drugs, this situation is put in very clear words by Sir R. Jacob: "The few winners must pay for all the losers."[19]

---

14 The survey was conducted by Biotechnology Innovation Organization that is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. It analyzed individual drug program phase transitions for ten years, from January 1, 2006 to December 31, 2015. Its world largest database includes 7,455 clinical drug development programs, across 1,103 companies.

15 Biotechnology Innovation Organization, Clinical Development Success Rates 2006-2015 (June 2016), https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.

16 *Id.* at 16.

17 Dickson et al., *supra* note 4.

18 Tudor I. Oprea, Current trends in lead discovery: *Are we looking for the appropriate properties?* 16 J. Comp.Mol.Des. 325, (2002).

19 Robin Jacob, IP and Other Things: A Collection of Essays and Speeches 233 (Oxford and Portland, Oregon 2015).

https://doi.org/10.5771/9783845294018-12, am 12.10.2024, 08:13:46
Open Access – (cc) BY – https://www.nomos-elibrary.de/agb

D. Significance of patents as safeguard of innovator's profits

As described above, the development of a new drug is cost intensive and highly risky business for pharmaceutical companies, requiring them to invest high R&D cost and take a risk of high failure rates. On the other hand, the duplication of the new compound is a simple technical matter. This is an especially important issue in the pharmaceutical research because the development of a new drug involves the long lag time from discovery of a novel compound to marketing.[20] A pharmaceutical company as an innovator needs to exclude the following third party who tries to copy its invention from the market until they recoup their investment and make enough profits for further innovation. That's the reason why it always needs patent protection for a new drug. Patent is the legal protection that is the exclusive right for a limited period of time regarding the new and inventive invention. This patent protection allows a pharmaceutical company to have enough time to recoup their significant investment in R&D. Without patent rights, competitors can simply copy biopharmaceutical innovations as soon as they are proven safe and effective, offering their own versions in the market without investing the time and money to develop the drug. Innovators in the pharmaceutical industry could lose the ability to recoup their substantial investment in a new drug development, making it more challenging to find funding. In this way, patent protection in the pharmaceutical industry is significant as safeguard of innovator's profits.

20 Dickson et al., *supra* note 4.

https://doi.org/10.5771/9783845294018-12, am 12.10.2024, 08:13:46
Open Access – (cc) BY - https://www.nomos-elibrary.de/agb