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Pharmaceutical Patent Protection in Turkey

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Abstract

Between 1994 and 1995, Turkey conducted necessary legislative studies to establish an efficient and contemporary industrial property system and obtained very important concrete results. Turkey has ratified many international agreements regarding the IP system and as a result of this, pharmaceutical products and their process procedures have also started to be protected by Intellectual Property (IP) rights since 1st January 1999. This means an important Turkish Industrial Property Revolution.

The international agreements regarding the IP system are, PCT (Patent Cooperation Treaty) which has come into force in 1st January 1996 and the EPC (European Patent Convention) in 1st November 2000. As a result of these changes, Turkey has some problems as other developing countries during the transition periods concerning their IP system.

Development of Pharmaceutical Patent Rights in Turkish Law

The first patent protection started in Ottoman Empire in 13th March 1879, with `Ihtira Berati Kanunu` which was inspired from French Law of 1844. According to this Law, the 3rd Article gives no protection right for the pharmaceutical products used for human and animal health. There was also no protection for the process of the products according to this patent law.

According to Article 27 TRIPs, which was come into force in 1st January 1995 in Turkey, it was stated to give the patent protection rights for all the inventions related to the product and process in all technical fields. Also according to Article 70/b.8 TRIPs, the countries which have no patent protection rights for the pharmaceuticals, has the right for to develop a method which gives the patent protection right for the pharmaceuticals. Thus, Turkey started to accept the patent applications for pharmaceuticals after 1st January 1995.

Accordingly, the new patent law which is Decree Law No. 551 pertaining to the Protection of Patent Rights (hereinafter referred to as "DL 551") was come into force at 27th June 1995.

Besides, Turkey has the right as a newly developing country, to postpone the pharmaceutical product and process patent protection for 4 years (Art.65(2) TRIPs) and another 5 years (Art. 65(4) TRIPs) according to the transitional provisions. As a result of this, when the DL 551 has come into force, the patent protection for the pharmaceutical products and processes were out of patent protection for 9 years. Accordingly after the acceptance of the TRIPS, the rules will not be in force for 1 year (Acceptance date is 26th January 1995), which makes 10 years postpone for the pharmaceutical patent protection. That means, the patent protection for the process of pharmaceutical products would be postponed until 1st January 2000, and the patent protection for the pharmaceutical products would be postponed until 1st January 2005.

Meanwhile the consultations were ongoing for the membership of Turkey for the European Union, it was foreseen to enter the European Customs Union in 1st January 1996. According to this, Turkey has to harmonize Decree law and regulations. As a result, the patent protection for the pharmaceutical products and process has to be start in 1st January 1999, so that Turkey lost its 1 year postpone right for the patent protection for the process of pharmaceutical products and 6 year postpone right for the patent protection of pharmaceutical products. This means an important Turkish Industrial Property Revolution.

Accordingly, the patent applications are accepted from the date of 1st January 1995 and waited without examined until 1st January 1999, so that all the patent applications which have a priority date of 1st January 1994 had the right for the patent protection after 1999 in Turkey.

Meanwhile, Turkey has ratified many international agreements regarding the IP system. The international agreements regarding the IP system are, PCT (Patent Cooperation Treaty) which has come into force in 1st January 1996 and the EPC (European Patent Convention) in 1st November 2000. As a result of these changes, Turkey had some problems as other developing countries during the transition periods concerning their IP system as mentioned above.

At the beginning, this results a chaotic situation among the generic market, because they have to wait up to max. 20 years for marketing a new product. As a result, an innovative approach had to rise up in Turkey after year 2000s in pharmaceutical industry among the Turkish pharmaceutical companies.

Patent Related Problems in the Generic Pharmaceuticals

Generic medicines play an important role in promoting pharmaceutical innovation and ensuring the affordability and sustainability of healthcare systems. Increasing the use of generic medicines creates competition in the pharmaceutical markets which stimulates innovation, promotes cost containment, and increases access to healthcare treatments to patients. In this regard, immediate market access of generic medicines after patent expiry is of crucial interest to society, and any hurdle to this rapid access should be eliminated.

There is little doubt that patent protection is necessary in the pharmaceutical sector as upfront research and development costs are substantial. Both originator and generics participants in the pharmaceutical industry support the patent system as a cornerstone of a legislative system that seeks to provide incentives for innovation. However, the invention that sits at the centre of a patent must truly warrant the granting of a monopoly right. Once granted, abuses and the inappropriate extension of that monopoly right should be prevented.

On the other hand, as other pharmaceutical generics among the world, Turkey has the same patent related problems, in which the patent system and the surrounding legal and regulatory framework fail to ensure an appropriate balance between incentives and competition such as with follow-on patent applications. Follow-on patent applications are the patent applications which the originals try to lengthen the protection of the molecule patents with other formulation patents such as polymorphs, hydrates, salts or isomers of the molecule patent, intermediates, process related patents, dosage forms, second medical use patents, particularly where that use is in a related field to the one originally disclosed in the first patent or a variation of the dosage regime already disclosed.

Formulation patents are an incredibly important aspect of lifecycle management from the perspective of the innovator, often blocking generic firms from competing with one or

more of the dosage forms offered by the innovator until sometime after molecule patent expiry. Where there is significant health or safety advantage in that particular protected dosage form over others in the product range and no generic equivalent is offered, such protection can be crucial in maintaining post-generic revenues. Conversely, where use of the protected dosage form offers no advantage in terms of the health or safety of the patient, the interest of cost minimization by the prescriber or dispenser will result limited benefit from such patenting as the cheaper alternative dosage form offered by a generic competitor will be dispensed. [2]

Somewhat in between these scenarios lies the most common one, where a generic competitor has developed a bioequivalent dosage form to one that is protected by a formulation patent, but has not infringed the formulation patent in doing so. The value of patent protecting the innovator formulation depends on acceptance of the equivalent generic dosage form by consumers and healthcare professionals. [2]

One further situation where formulation patents are important is where a generic competitor develops a dosage form that, in itself, is an addition to the innovator product line and offers advantage over the existing product. This may be an additional strength, a more storage stable formulation or a dosage form that increases patient compliance that somehow benefits from patent protection owned by the generic competitor, or by a third party who has licensed it out. [2]

Another important situation occurs in divisional patent applications when patentee is filing a divisional application that is essentially identical with the parent application. One reason for this type of divisional filing could be the parent patent is about to death. Therefore, they sometimes cause similar problems for the generics but with the new Rule 36 EPC which came into force in 1st April 2010, this problem is trying to keep in minimized in EP patent filing system.

Patent litigation procedures open to abuse by patentees

Once a patent is granted, it is most valuable to a patentee when the rights conferred by it are exercised through litigation in each market and the monopoly rights are enforced. There is nothing inherently wrong with exercising patent rights, but in certain circumstances this might result in abusive and anticompetitive behavior. It is clearly proper that a right holder has the opportunity to exercise his rights in court and to try to enforce them against a party believed to be infringing upon those rights. However, a patentee should want to resolve the issues at the earliest possible opportunity after becoming aware that an issue exists, and should not be permitted to delay. Situations where the right holder makes no effort to resolve the dispute because the status quo is favourable to him and deliberately misrepresents a situation purely for commercial gain clearly constitute an abuse of the judicial system. [3]

Not only the behavior of the patentee, but also the litigation framework itself, often creates problems and disadvantages for generic medicines companies. In general, the types of conduct and structural problems regarding patent litigation can be identified as follows; [3]

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[2] "Formulation patents in pharmaceutical development (Leighton Howard, Journal of Generic Medicines, July 2008).

[3] Patent-related barriers to market entry for Generic Medicines in the EU (Kristof Roox et al., European Generic Medicines Association (EGA), May 2008).

- The complexity and unpredictability of litigation,
- Improper granting of interim injunction,
- The length of the proceedings on the merits (non-infringement and/or invalidity proceedings),
- Split infringement and invalidity courts,
- Inability to disclose information on a confidential basis.

There are also other patent – related barriers such as;

- Patent linkage,
- Statements to authorities,
- Shifting consumer demand with marketing campaigns,
- SPC granted on the basis of incorrect information.

Recommendations [3]

To overcome the problems outlined above, the following modifications to the current legal and regulatory environment related to pharmaceutical patents are suggested:

1. To improve patent quality:

a. provide adequate resources and continue to encourage the Patent Offices to improve the quality of patents that are granted by applying a consistently high standard of thoroughness in patent examination by well-trained examiners;

b. require patentees to file high quality applications and introduce the duty of candour to ensure that all information relevant to the patent being examined by the Patent Offices is disclosed by the applicant;

c. introduce a mechanism (prosecution history estoppel) whereby patentees are held accountable for statements made during prosecution when a patent is being litigated;

d. guarantee that interested parties have sufficient opportunity to alert the Patent Offices about questionable patents within the granting process itself; and

e. accelerate the opposition procedure.

2. To prevent the creation of patent thickets and reduce the incidence of poor follow-on patents:

a. improve the quality of patents as outlined above and apply a rigorous assessment of patentability requirements;

b. prevent the filing of divisional patents that are essentially identical to the parent application;

[3] Patent-related barriers to market entry for Generic Medicines in the EU (Kristof Roox et al., European Generic Medicines Association (EGA), May 2008).

c. require that patent claims with respect to the pharmacokinetic effect of administering a particular drug be directly linked to the formulation used to achieve that effect;

d. limit the scope of second and further medical use patents; and

e. grant patents only to genuine incremental innovation and not to simple changes in chemistry or formulation.

3. To improve the patent litigation system in order to avoid excessive and abusive litigation and diverging and unbalanced decisions:

a. create a national litigation framework with technically qualified and experienced patent judges who can reach a decision on the merits of a case within a reasonable period of time;

b. avoid interim injunctions by inexperienced judges without a proper assessment of the rights of all the various parties involved;

c. require common standards of evidence and a duty on all parties to the litigation to present evidence to the court both for and against awarding a preliminary injunction;

d. involve the health care authorities in patent proceedings, particularly in applications for interim injunctions;

Conclusion

It is clear that formulation patents cannot be ignored in developing a generic pharmaceutical product due to the large amount of incremental patent filings witnessed for certain products. In fact, some formulation patents may be used to the advantage of generic entrants where they add significant value to the existing product line by use of truly innovative, patent protected formulation (or device) technology. Accordingly, only true inventors should be rewarded with patents to both innovator and generic applicants, so that generic competition can reduce risk and carry on with the business of developing low-cost, bioequivalent and fully substitutable products for the benefit of the patient and healthindustry. Therefore, comprehensive patent searching and ongoing monitoring of pending patent applications and new publications are essential in managing the risk inherent in developing formulations for generic pharmaceutical products.

References:

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Sanovel Ilac (Pharmaceuticals) is the fastest growing company in the Turkish pharmaceutical market, was been established in 1983 by Pharmacist Erol Toksoz and has grown to be the flagship company in core business of Toksoz Group that manufactures, markets and distributes pharmaceutical products. Moving up in IMS ranking to be among top ten companies over the last decade, Sanovel has proven success record of developing and introducing value added and patented generic products to market in all vital therapeutic areas.

Furthermore, Sanovel serves in animal health with its veterinary products.

While growing in Turkey, Sanovel is also moving towards international recognition. Branch offices are already established in CIS, Ukraine and Russian Federation. Export to Georgia and Azerbaijan has started in 2005. At the same time the project for presence in EU and USA is also moving forward with companies established in Netherland (Adilna Sanovel Holding B.V.), France (Sanovel S.A.S), Germany (Sanovel GmbH) and Bulgaria (Sanovel L.L.C).