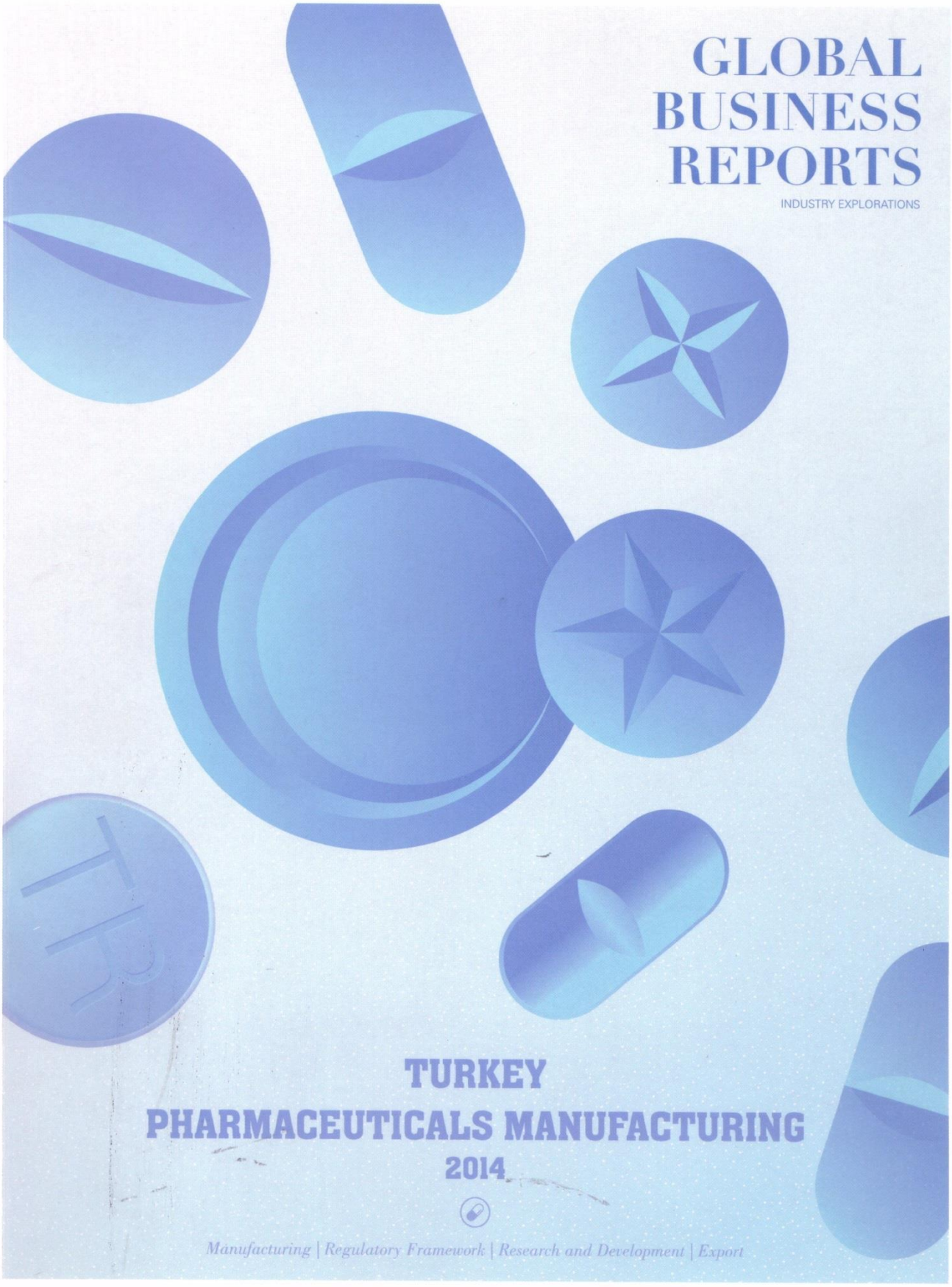

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PHARMACEUTICAL PATENTS IN TURKEY: The State of Turkish Patent Protection and Challenges Remaining to the Implementation of an Effective Legal Framework for Patent Protection in Turkey

by Cahit Suluk

I. The Process of Incorporating Drugs under Patents

A regulatory system governing patent protection in Turkey vvas first adopted during the Ottoman period under the "Patent Law of 1879," vvhich vvas the sixth patent lavv system to be estab- lished in the vvorld. Inspired by the French "Patent Lavv of 1844," the lavv excluded pharmaceutical products from patent protection under article three. This system vvas abolished in 1995. Important reforms in Turkey have almost alvvays been introduced as a result of external influences. This tradition has also been followved vvith respect to intel- lectual property in general; hovvever, for pharmaceutical patents this has been es- pecially true. Patent protection for pharmaceuticals under Turkish lavv first took effect after Turkey became a member of TRIPS and followving the signing of a customs union vvith the EU, on January 1st of 1999. As a developing country, Turkey vvas granted a transition period under TRIPS: until January 1st, 2000, ensure that its manufacturing practices vvere up to date and until January 1st of 2005 in order to ensure that its compliance vvere TRIPS-compliant. Legal protection for pharmaceutical patents has extended from the TRIPS system.

II. The Bolar Provision

Under Turkish lavv, the Bolar exemption has been applied broadly. Accordingly, the "activities fortrial purposes involving an invented drug, including registration of the drug as well as tests and trials required for registration," are exempted from patent protection (Decree-Lavv on Patents, Art. 75/f).

As per the Bolar exemption, a generic firm is allovved to conduct a bioequiv- alence study and to apply for drug registration before the expiration of the patent term, so that a generic drug can be introduced to the market the day im- mediately followving the expiration of a patent term. If the generic firm is unable to conduct the bioequivalence study and to apply for the registration of the drug during the term of patent protection, the patent term of 20 years will extended. Neither the drug registration authority in Turkey, nor the Turkish judiciary, ac- cepts the making of an abridged drug application, or even granting drug registration for a generic drug as a patent infringement. Hovvever, because sales permission for a generic drug granted by the registration authority automatically reduces the price of the original drug by 40%, this is accepted as a patent infringement.

III. Pipeline Protection

When drafting TRIPS, it vvas proposed that drugs protected by patents in coun- tries recognizing pharmaceutical patents also be taken under patent protection in those countries, such as Turkey, vvhich have subsequently recognized pharmaceutical patents. İn this vvay it vvas in- tended that inventions vvhich are not nevv but vvhich have been patented in other countries also be registered in countries subsequently recognizing pharmaceutical patents. Turkey has not accepted this means of protection, referred to in the literatüre as pipeline protection, on the grounds that it is under no obligation to do so; neither under the terms of any international treaty nor under the terms of its relations vvith the EU.

IV. Supplementary Protection Certificate

An average of 8 to 12 years passes from the date of application for pharmaceutical patent until the introduction of the drug onto the market. For this reason, a patent protection of 20 years can be used for only 10 to 12 years. İn order to prevent this loss of time, vvhich is called the "bitten term", some developed countries have adopted a supplementary protection certificate particular to drugs. The EU has mandated that Turkey intro- duce regulations concerning this supplementary protection, hovvever Turkey has rejected this demand on the grounds that it has undertaken no commitment in this regard either under TRIPS, or Deci- sion No. 1/95 of the Association Council. The supplementary protection certificate is not currently on the agenda in Turkey.

V. Data Exclusivity

Another intellectual property protection measure specific to drugs is data exclu- sivity. The discussions över Article 39/3 of TRIPS aside, the duration of data ex- clusivity protection vvas 6 years in the EU at the time vvhen Decision No. 1/97 of the Association Council vvas adopted. For this reason, Turkey has accepted a data exclusivity period of six years. Hovvever, the EU subsequently extended this period to 8+2+1 years. The EU has mandated that Turkey adopt this regulation, hovvever Turkey has refused to do so on the grounds that it is under no obligation in this regard under Decision No. 1/97 of the Association Council. Turkey has de- clared that it will fulfill this requirement only after attaining full membership of the EU.

The practice of data exclusivity under the Regulation on the Registration of Medici- nal Products for Hurman Use 2005, which is stili in effect, is as followvs in summary: Before 1.1.2005 - If the original firm vvithin the EU-Turkey customs union registers a drug after 1 January 2001 but does not make any application for generic in Turkey until January ist, 2005, such a drug is granted data exclusivity for six years (but being limited to the term of the patent) from the date of first registration of the drug vvithin the customs union. After 1.1.2005 - If original drugs are reg- istered for the first time vvithin the cus- toms union after January 1st, 2005, such products are granted data exclusivity for a period of six years (but being limited to the term of the patent) from the date of first registration vvithin the customs union.

As per the practice in Turkey, data exclu- sivity does not preclude the generic firm from making an abridged application for registration and carrying out the registration formalities. Hovvever, once the drug registration certificate has been obtained, right arising from data exclusivity may be claimed.

VI. Patent Law?

Apart from the patent lavv of 1879 passed during the Ottoman era, there has been no patent lavv enacted by the parliament of Turkey. Decree-Lavv No. 551 is not a lavv, but a disposition of the govemment. The basic reason for this is pharmaceu- tical patents. The reason vvhy Turkey refrained from becoming a party to the European Patent Convention (EPC) for a prolonged time, although it vvas one of the founders of the International Patents Institute, is that the government vvished to exclude pharmaceuticals from patent protection. As a result of the inclusion of pharmaceuticals under patents since January 1 st, 1999, after the establishment of the customs union vvith the EU in 1995, no excuse remained for Turkey to not accept the EPC. Thus, Turkey has been party to this convention since the 1 st of November, 2000. During the discussions concerning TRIPS, vvhich lasted nine years, the only issue brought forvvard by Turkey vvas pharmaceutical patents. A draft lavv consisting of approximately 100 articles proposing amendments to the legislation on industrial property rights, including Decree-Lavv No. 551 on patents, has recently been submitted to the general assembly of the parliament. İn the discussions över the draft, vvhich bears the marks of an ad hoc, patchvvork affair, the issue under discussion vvas, once again, predominantly pharmaceutical patents. İn sum, there is, as yet, no patent lavv in sight on the horizon. •

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