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Report Q202

in the name of the Turkish Group
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The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

Yes, according to Article 75(b) of Decree-Law No. 551 on the Protection of Patent Rights (hereafter "DL 551"), acts involving the patented invention for experimental purposes shall remain outside the scope of rights conferred by a patent. Scope of the experimental use exception is not specified in Article 75(b). On the other hand, according to Article 75(a), acts devoid of any industrial or commercial purpose and limited to private ends/aims shall remain outside the scope of rights conferred by a patent. Accordingly, it is possible to evaluate Article 75(b) in terms of Article 75(a) and argue that experimental use is not permitted for commercial purposes. On the other hand, Article 75(b) is worded in such general terms that it may be argued that experimental use is permitted for commercial purposes.

2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

Yes, it is recognized under DL 551. Bolar-type exception is implemented in Turkey on 22.06.2004 by the addition of Article 75(f). Limits of the scope of rights conferred by a patent are defined in Article 75. It states that third parties can apply for marketing authorization and perform tests and experiments required for the authorization of medicaments while the patent is in force. While "medicaments" are not defined in DL 551, it may be argued that this exception does not apply to biological products or research tools. DL 551 and draft copy of the new patent law narrowly defines the pre-expiry exemption to testing for marketing authorizations, but leaves room for interpretation indicating that stockpiling etc. may be acceptable.

Article 75
The following acts shall remain outside the scope of rights conferred by a patent:

a) Acts devoid of any industrial or commercial purpose and limited to private ends/aims;

b) Acts involving, for experimental purposes, the invention, subject matter of a patent;

c) Extemporaneous preparations of medicines in pharmacies involving no mass production and carried out solely in making up a prescription and acts related to the medicines thus prepared;

d) Use of patented invention in the manufacture or operation of ships or spaceships or airplanes or land transportation vehicles of countries signatory of the Paris Convention or for satisfying the needs of these, provided that said vehicles happen to be, temporarily or accidentally, within the boundaries of the Republic of Turkey;

e) Where acts provided under Article 27 of the International Convention for Civil Aviation dated December 7, 1944 are related to an aircraft of a State, the provisions of this present Article shall apply likewise to said aircrafts.

f) Registration of medicaments and acts involving the subject matter of the invention for experimental purposes in order to obtain marketing authorization for medicinal products, including the required tests and experiments for this purpose.

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

Parallel imports of patented medicines, medical devices or other pharmaceutical products are not allowed according to DL 551 and pharmaceutical products authorization regulations.

Rights on the products that are subject to the trade should be exhausted to do parallel trade. Exhaustion of rights is mentioned in DL 551 Article 76 which is in force since 27.06.1995 and states that "rights conferred by a patent shall not extend to the acts committed with regard to a product under patent protection after said product has been put to sale in Turkey by the right holder of the patent or with his consent". In other words national exhaustion principle is accepted according to this Article by the "product, under patent protection, has been put to sale in Turkey" expression.

Meanwhile there is a customs union agreement between Turkey and the European Union. And according to the EC- Turkey Association Council Decision 1/95, in which EU-Turkey trade relations are regulated, parallel trade is agreed as follows; "this decision does not imply exhaustion of intellectual, industrial and commercial property rights applied in the trade relations between the two Parties under this Decision". Considering this Article, regional exhaustion is not possible between Turkey and EU for intellectual, industrial and commercial property rights.

Exhaustion of Rights Conferred by a Patent
Article 76:
Rights conferred by a patent shall not extend to acts committed with regard to a product under patent protection after said product has been put to sale in Turkey by the right holder of the patent or with his consent.

EC-Turkey Association Council Decision 1/95 Annex 8 Article 10.
The Parties agree that for the purpose of this Decision, intellectual, industrial and commercial property includes in particular copyright, including the copyright in computer programmes, and neighbouring rights, patents, industrial designs, geographical indications including appellations of origin, trade marks and service marks, topographies of integrated circuits as well as protection against unfair competition as referred to in Article 10a of the Paris Convention for the protection of industrial property and protection of undisclosed information on know-how.

165. This decision does not imply exhaustion of intellectual, industrial and commercial property rights applied in the trade relations between the two Parties under this Decision.

On the other hand, as thoroughly explained in the answer to Q205 "Exhaustion of IPRs in cases of recycling and repair of goods," Part I (Analysis of the current statutory and case laws), Question 2 as to exhaustion of rights regarding patents, designs and trademarks, the system of national exhaustion is applied in Turkish law, however to date 11th Chamber of the Supreme Court rendered decisions as if the principle of international exhaustion is applied. It is important to note that these decisions do not relate to patented medicines, medical devices or other pharmaceutical products, however we presume that the Court would apply the principle of international exhaustion in a case involving above-referenced goods.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

Yes, Art. 75(c) of DL 551 addresses an exception for individual prescriptions, provided that medications are produced in a pharmacy shop extemporaneously and not in mass form. Acts relating to the medicines thus prepared are also deemed to be outside the scope of protection conferred by a patent. There are no other provisions that limit an extemporaneous preparation of an individual prescription.

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

No, methods of medical treatment are **NOT** patentable according to DL 551.

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

Yes the compulsory licenses are available under the Article 99 of DL 551: Compulsory license is (to be) granted where no offer for licensing has been made and where any one of the following situations/conditions materializes:

- Failure to put to use/work the patented invention;
  The delay in the use of the patent was not due to justifiable/legitimate reasons or the use thereof had been suspended during an uninterrupted period of 3 years without justifiable/legitimate reason".

- Dependency of subject matter of patents as mentioned in Article 79:
  This Article concerns the possibility of using the subject matter of a patent with the subject matter protected under a prior patent. The right holder of the prior patent and the right holder of the latter patent may not use the patent of the other party, without his consent, during the term of the validity of his patent. However the right holder of the latter patent may use also the prior patent upon authorization of the right holder of the prior patent or in case he has been granted compulsory license to use said prior patent;

- On grounds of public interest as mentioned in Article 103:
  The Council of Ministers decides for the grant of the compulsory license on grounds of public interest when the subject matter of the patent concerns topics like public health, national defense. Situations where the non-use of the invention or its insufficient use in terms of quality and quantity, causes serious damage to the country's economic or technical development shall be deemed to also involve public interest.

The compulsory license is not exclusive. Only, the compulsory license on grounds of public interest may be granted as an exclusive license.

There are no compulsory licenses granted in Turkey for the domestic manufacture and supply of pharmaceutical products.

7) *Has new Article 31bis TRIPS been ratified in your country? Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003? Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.*

No, new Article 31bis TRIPS has not been ratified in Turkey and there are no other legislative amendments in effect. On the other hand, the draft copy of the new patent law includes provisions as to the grant of compulsory licenses for exportation of pharmaceutical products due to public health reasons to countries unable to manufacture the products or do not have sufficient capacity to manufacture the products. We cannot foresee when the new patent law will come into effect. There are no compulsory licenses granted in Turkey for the importation or exportation of pharmaceutical products.

8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

No.

9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

No.

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

DL 551 does not recognise further means of facilitating access to medicines, medical devices, and diagnostics.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
  The Turkish Group is of the opinion that patent law should provide for research or experimental use exception for scientific/academic purposes to promote scientific innovation, however not for commercial purposes. Application of this exception for scientific/academic purposes may contribute to improvements in the health sector and to improved products/pharmaceuticals. On the other hand, we are of the opinion that authorizing experimenting on an invention for commercial purposes will infringe the patent owner's rights. A balance between interests of public at large and interests and rights of a patent owner must be maintained.
- *Bolar exception;*
  This provision allows not only performing tests and experiments required for the authorization but also registration of medicaments.

  The scope of Bolar-type exception is not certain in Article 75(f) of DL 551. We propose that the scope of this exception may be extended in order to launch generic product in the market as of the 1st day on which the patent protection for that medicament expires.
- *parallel import of patented medicines;*
  National exhaustion is accepted in Turkey and parallel trade between EU and Turkey

is not allowed although customs union exists. As mentioned in Q205 "Exhaustion of IPRs in cases of recycling and repair of goods," Part II (Proposals for uniform rules), Proposal 6, the Turkish Group is of the opinion that EU Directives and Turkish law should be harmonized, thereby regional exhaustion should be adopted in Turkish law and implemented within the borders of Customs Union. Parallel trade of medicines and medicinal products may help lowering their price and help accessibility of drugs in Turkey regarding public health.

– *individual prescriptions exception;*
Yes, it is believed that the patent law should allow an exception for preparation of individual prescriptions. In spite of the fact that an exception may mean delimitation of rights of a patentee, it is believed that corresponding provisions in the law considerably limit the scope of the exception, and hence, eliminate the possibility of its use to cover commercial uses of a patented medicine. These provisions are believed to be sufficiently defending rights conferred by a patent while providing a certain degree of flexibility for those in need of personal exploitation of a patented medicine.

– *medical treatment defence;*
This would be the case if the patent law had provided protection for methods of treatment. While this is not the case in DL 551 and hence no proposal will be made, it is found preferable to prevent medical treatment methods from being patentable subject matter for protecting public health in general.

– *compulsory licensing;*
National patent laws should allow compulsory licensing for using a patented invention without the patent owner's consent, by taking into account some provisions mentioned below:

  i) the compulsory license may be restricted and may depend on conditions, like extend and duration of use,

  ii) patent owner should receive a reasonable royalty from the compulsory license,

  iii) the patentee may raise a complaint to lift the compulsory license, when the circumstances have been changed.

  Moreover the patent law should provide for compulsory license considering that the public health and the national defense remain the main targets to be protected by a government. Topics like public health and national defense prevail over the exclusive right conferred by the patent to his owner. This is the reason that in most countries provisions of compulsory license are included in the national patent laws.

  This is also supported by the draft copy of the new patent law, which contains more detailed provisions of compulsory license to be granted by court, which in addition to the grounds already existing has added the condition of granting compulsory license in case of exportation of pharmaceutical products to countries for reasons of public health problems.

– *expropriation;*
Expropriation of a patent by the government should be allowed only in state of war or widely distributed outbreak of epidemic diseases.

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

In compulsory license cases, the government may provide some provisions in national patent law aiming to extend the term of protection of patent, in case the owner of the patent agreed to give a license or even transfer of know-how of producing the required patented medicines

in public health crises or other serious conditions, such as war. In these provisions, the term of protection shall be extended with a period equal to the term of compulsory license.

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

We believe that it is fairly difficult, if not impossible, to harmonize limitations of patent rights such as the research and experimental use exception, Bolar exception or the individual prescriptions exception. The primary reason is the highly heterogeneous social and economical structure of different countries and their individual regions or states. Each country has the right to defend its own interests when regulating or at least interpreting the limits of these restrictions. A secondary reason would be the inevitable result of practically inapplicable provisions in a large bundle of national laws.

Summary

The Turkish Group is of the opinion that patent laws should provide for exceptions regarding health-sensitive issues with a view to protecting public health to the extent that these are allowed only for non-commercial purposes. Particularly, the scope of this exception may be extended in order to launch generic product in the market as of the 1st day on which the patent protection for that pharmaceutical product expires. With regard to the harmonization of limitations, we believe that it is fairly difficult, if not impossible, to harmonize these exceptions worldwide. While one of the reasons for this finding is the highly heterogeneous social and economical structure of different countries or regions which might lead these provisions practically inapplicable, a second one might be the inevitable right and need for a particular country to defend its own interests when regulating or at least interpreting the limits of these restrictions.

Résumé

Le Groupe Turc est de l'avis que les lois sur le brevet doivent prévoir des exceptions sur des cas sensibles touchant à la santé dans le but de protégér la santé publique et dans la mesure où de telles exceptions sont uniquement prévues pour des fins non-commerciales. Particulièrement, la portée de cette exception pourrait être étendue envue de lancer le produit générique dans le marché à partir du premier jour de l'expiration de protection du produit pharmaceutique. En ce qui concerne l'harmonization des limitations, nous estimons qu'il est assez difficile, sinon impossible, d'harmoniser ces exceptions à l' échelle mondiale. Alors qu'une des raisons de cette constatation est fortement liée à la structure hétérogène sociale et économique de différents pays ou régions qui pourrait aboutir à l'inapplicabilité pratique de ces dispositions, une seconde raison pourrait être le droit indispensable et le besoin pour un pays particulier de défendre ses propres intérêts lorsqu'il règle ou tout au moins interprète les limites de ces restrictions.

Zusammenfassung

Die türkische Gruppe vertritt die Meinung, dass die Patentgesetze bei Fragen der öffentlichen Gesundheitspflege zum Schutz der öffentlichen Gesundheit Ausnahmen zulassen sollte, wenn diese ausschliesslich nicht kommerziellen Zweck dienen. Als besonderer Punkt, kann der Rahmen dieser Ausnahme für das Inverkehrbringen von Generikum vom ersten Tag an ausgedehnt werden, an dem die Patentschutz für dieses Arzneimittel verfällt. Hinsichtlich der Harmonisierung der Ausnahmen und Einschränkungen zukünftiger Verordnungen glauben wir, dass eine weltweite Harmonisierung nicht unbedingt unmöglich aber bestimmt sehr schwierig sein wird. Diese Stellungnahme wird

erstens durch die Behauptung begründet, dass verschiedene Länder und Regionen über recht verschiedenartige soziale und ökonomische Strukturen verfügen, und dies wiederum dazu führen kann, dass derartige Verordnungen praktisch unausführbar werden. Als zweite Begründung wird aufgeführt, dass im Rahmen der Verteidigung des Staatsinteresse das Recht die Grenzen dieser Ausnahmen und Einschränkungen festzulegen oder mindestens zu interpretieren im Ermessungsspielraum der einzelnen Länder liegen sollte.