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Report Q202

in the name of the Portuguese 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?

Yes, in accordance with paragraph c) of Article 102 of the Portuguese Industrial Property Code – IPC *("Limitation of the rights conferred by a patent")*:

"The rights conferred by a patent shall not cover:

c) Acts carried out exclusively for testing or experimental purposes (…)".

If so, under which conditions? What is the scope of the research exception?

"(…) although the industrial or commercial working of such products cannot begin before the patent which protects them has lapsed" (Article 102(c) in fine).

The scope of use for testing or experimen¬tal purposes covers, in particular, scientific acts in the field of research, including in-house tests and experiments.

Specifically, is research or experimental use permitted for commercial purposes?

Portuguese law does not expressly provide that use within the scope of tests or experiments cannot be carried out for commercial purposes.

Accordingly, commercial purposes *per se* in the abovementioned field are not legally prohibited.

However, commercial purposes naturally do not include the actual commercial working of the product resulting from experiments or tests. In fact, it is necessary to bear in mind the express limitation laid down in the law, i.e. *"(…) although the industrial or commercial working of such products cannot begin before the patent which protects them has lapsed" (Article 102(c) in fine).*

2) Is a Bolar-type exception recognised under your patent law?

Yes, in accordance with paragraph c) of Article 102 of the IPC (*"Limitation of the rights conferred by a patent"*):

"The rights conferred by a patent shall not cover:

c) Acts carried out exclusively for testing or experimental purposes, including experiments for the preparation of the administrative procedures necessary for the approval of products by the competent official bodies (…)".

If so, under which conditions? What is the scope of the Bolar exception?

The conditions are limited to the *preparation of the administrative procedures necessary for the approval of products by the competent official bodies.*

In Portugal, the commercialisation of medicinal products requires the prior administrative authorisation of the National Health and Drug Agency (INFARMED), which is responsible for the approval of authorisations to place products on the market (Marketing Authorisations – MAs).

The statute which regulates this matter is Decree-Law no. 176/2006 of 30th August 2006 (known as the *Medicinal Product Statute*).

The MA normally leads to a subsequent and necessary approval of the price of the medicinal product by the Portuguese Department of Economic Activities, in accordance with Decree-Law no. 65/2007 of 14th March 2007.

Generic drugs for which MAs and public price approval have been obtained are sold at a price which is 35% lower than the price of the original drug, in accordance with Decree-Law no. 65/2007 of 14th March 2007.

It is also necessary to take into account that the abovementioned Decree-Law no. 176/2006 of 30th August 2006 provides in Article 19(8) that *"Notwithstanding the provisions of Article 102 of the Industrial Property Code, the conducting of the studies and tests necessary for the application of paragraphs 1 to 6, and the practical requirements arising therefrom, do not go against the rights relating to patents or to supplementary protection certificates for medicinal products."*

Thus, the use of chemico-pharmaceutical products which are protected by patents that are valid and in force is permitted for the purpose of the said studies and tests, within the scope of the administrative procedures for the approval of medicinal products.

However, once again, the abovementioned legal limitation within the scope of the IPC must be borne in mind, i.e. *"(…) although the industrial or commercial working of such products cannot begin before the patent which protects them has lapsed"* (Article 102(c) *in fine).*

Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.?

The law is not expressly limited to drugs, meaning that there is no reason to sustain that the Bolar exception does not also apply to 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?

This is not applicable, in view of the fact that Portuguese law specifically contains a Bolar provision/clause.

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?*

This matter is related to the exhaustion of the right as provided, with regard to patents, under Article 103 of the IPC, which states as follows:

"1. The rights conferred by a patent shall not allow the patentee to prohibit acts relating to the patented products after they have been put on the market, by himself or with his consent, in the European Economic Area."

That is to say, exhaustion of the right at Community level is expressly provided for, but international exhaustion is not.

Thus, there is no provision in Portuguese law providing for international exhaustion.

In any case, the aforementioned *Medicinal Product Statute* (Decree-Law no. 176/2006 of 30th August 2006) contains a section devoted to parallel importation, wherein the conditions under which it is permitted and the respective requirements are duly defined:

"1 – The parallel importation of medicinal products is subject to the following conditions and requirements:

a) A valid marketing authorisation has been granted for the medicinal product in the Member State of origin;

b) The parallel import is notified to the holder of the Portuguese marketing authorisation for the medicinal product concerned;

c) The parallel import is authorised on the terms provided in the present decree-law;

d) The medicinal product is commercialised in compliance with the conditions laid down in the present decree-law and other applicable legislation.

2 – Parallel importation is only permitted in the case of medicinal products which meet the following requirements:

a) In relation to the medicinal product concerned, they have the same quantitative and qualitative composition in terms of active substances, the same pharmaceutical form and the same therapeutic indications;

b) They have a common origin;

c) Where there is no common origin, authorisation does not constitute a risk to public health;

d) They use different excipients or excipients in different quantities without any therapeutic impact."

The entity responsible for authorising the parallel import is INFARMED, which verifies whether the abovementioned conditions and other formal requirements stipulated in the aforesaid law are met.

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

Yes, in accordance with paragraph b) of Article 102 of the IPC (*"Limitation of the rights conferred by a patent"*):

"The rights conferred by a patent shall not cover:

b) The preparation of medicines made instantly and for individual cases with a prescription in pharmacy laboratories, or acts related to medicines prepared in this way."

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?

Not applicable.

Portuguese law does not permit the protection, as a patent right, of *"surgical or therapeutic methods of treatment of humans or animals and diagnostic methods applicable to humans or animals shall not be patentable, although the products, substances or compositions used in any of these methods shall be patentable"* (Article 52(2) of the IPC).

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.)?*

Yes, in accordance with Article 107 of the IPC (*"Compulsory licences"*):

"1. Compulsory licences may be recorded against a certain patent in any of the following cases:

a) Non-working or insufficient working of the patented invention;
b) Dependency between patents;
c) For reasons of public interest."

Public interest is defined in Article 110(2) and (3) of the IPC:

"2. Reasons of public interest shall be considered to exist if the commencement, increase or generalisation of the working of the invention or the improvement of the conditions in which such working is effected are of supreme importance to public health or national defence.

3. Reasons of public interest shall also be considered to exist if failure to work the invention or insufficient working in terms of quality or quantity causes serious damage to Portugal's economic or technological development."

The conditions and requirements for compulsory licences are laid down in Article 107(2) to (7) of the IPC.

Furthermore, the aforementioned *Medicinal Product Statute* (Decree-Law no. 176/2006 of 30th August 2006) provides in Article 92(1)(a) and (b) two situations which fall within the concept of public interest, by express reference to the said Article 110 of the IPC, through Article 93(4) of the *Medicinal Product Statute*.

These situations are the following:

"INFARMED can authorise the use in Portugal of medicinal products not possessing the authorisations stipulated in the present decree-law under either of the following conditions:

a) When, based on clinical grounds, they are considered to be essential for the prevention, diagnosis or treatment of certain pathologies;

b) When they are necessary in response to the actual or potential spread of pathogenic agents, toxins, chemical agents or nuclear radiation susceptible of causing harm."

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, there was a case involving a patent whose subject matter was a plant protection product (Portuguese patent no. 76.136), in respect of which a compulsory licence was granted by the Portuguese Industrial Property Office on 31st October 2002 (Patentee: *Syngenta*; Licensee: *Sapec Agro*).

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.*

Article 31*bis* TRIPS has not yet been ratified in Portugal.

There are no other legislative instruments with a view to implementing the WTO decision of 30th August 2003. In any case, this decision can naturally be applied in Portugal, even

though there are no practical cases exemplifying specific situations in which the said decision has been taken into consideration by the Portuguese State.

Regarding compulsory licences, please see the reply to question 6).

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?

The short answer is no, i.e. without previous licence, the government cannot use a patent, not even for a type of "crown use".

However, although Portuguese law does not expressly permit this situation, it is possible to sustain the analogous application of Article 110 of the IPC, which stipulates that the owner of a patent may be compelled to grant a licence for the use or working of a patent, provided that the legal requirements which define public interest are duly met, and the potential licensees would include the State. Therefore, the State could force the owner of a patent to grant a licence in its favour, which would constitute a type of "crown use", but through the formal existence of a licence.

In fact, the abovementioned article of the IPC states that:

"1. For reasons of public interest the patentee may be compelled to grant a licence to work the respective invention."

Public interest is defined in Article 110(2) and (3) of the same legal statute:

"2. Reasons of public interest shall be considered to exist if the commencement, increase or generalisation of the working of the invention or the improvement of the conditions in which such working is effected are of supreme importance to public health or national defence.

3. Reasons of public interest shall also be considered to exist if failure to work the invention or insufficient working in terms of quality or quantity causes serious damage to Portugal's economic or technological development."

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

Yes, in view of the fact that Portuguese law provides as follows (in Article 105 of the IPC):

"1. A person may be legally deprived of a patent on account of contractual obligations with others or if the patent is expropriated for a public purpose.

2. Any patent may be expropriated for public purposes, against payment of just compensation, should it become necessary to make the invention accessible to the public or should its use by public bodies so require.

3. The terms of the Expropriation Code, with the necessary adaptations, shall apply."

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.

This is not applicable, as Portuguese law does not recognise these other means.

II) Proposals for adoption of uniform rules

1) Should patent law provide for

- *research and experimental use exception;*
- *Bolar exception;*
- *parallel import of patented medicines;*

– *individual prescriptions exception;*
– *medical treatment defence;*
– *compulsory licensing;*
– *expropriation;*
– *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

If so, under what circumstances? If not, why not?

As discussed in the replies set out above, Portuguese law provides for most of the normal limitations of patent rights, i.e. the research and experimental use exception, Bolar exception, parallel importation, individual prescriptions exception, compulsory licences and expropriation.

Thus, we consider that the provisions relating to legal limitations, on the precise terms on which they are defined, are in themselves sufficient for safeguarding issues concerning the public interest of public health, in general terms.

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?*

Bearing in mind what was stated in the previous reply, i.e. that the provisions relating to legal limitations are sufficient, we do not see any other limitations that might be useful for facilitating access to medicines, diagnostics, medical devices and the like.

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?*

Likewise, we do not believe that it would be advisable to harmonise the limitations in question, in view of the fact that each State has its own specific needs, which relate in particular to a market that is also specific.

Therefore, a harmonisation of the exceptions in question could prejudice these specificities of each State and leave no room for issues that need to be adapted to each market.

Nevertheless, since Portuguese law is sufficient and balanced in terms of its provisions regarding the limitations of patent rights, it could serve as the "basis", or at least as a "good example", for a possible harmonisation, even though some of the limitations provided under Portuguese law are naturally already the result of harmonisation within the field of Community/European Union law.

Summary

The protection of public health is one of the most relevant and pressing issues all over the world.

The "Patent System", and in the case of the present question chemico-pharmaceutical patents, promote scientific and technological innovation and, as a result, there have been significant advances in the treatment of diseases and general health conditions among the population.

Although they may naturally be compatible, what is under discussion here is the dual-faceted question of the protection of public health/"Patent System", in particular the ideal way in which they can be made to work together.

This is a complex issue, which involves many different aspects, with some of the main concerns relating to the capacity to manufacture/produce and commercialise/distribute (patented) medicines, especially during epidemics or pandemics.

In order both to resolve the abovementioned problem and to contribute towards research, the "Patent System" provides for limitations of the rights conferred by patents.

Some of these limitations are examined in the question under analysis, particularly in terms of "access" to chemico-pharmaceutical and biotechnological patents by third parties.

Portuguese law provides for most of the normal limitations of patent rights, i.e. the research and experimental use exception (Article 102(c) of the Portuguese Industrial Property Code), the Bolar exception (same article and paragraph), parallel importation (the IPC provides for exhaustion at Community level, but not international exhaustion), the individual prescriptions exception (Article 102(b) IPC), compulsory licences (Article 107 IPC) and expropriation (Article 105 IPC).

Article 31bis TRIPS, however, has not yet been ratified in Portugal and there are no other legislative instruments with a view to implementing the WTO decision of 30th August 2003. In any case, this decision can naturally be applied in Portugal, even though there are no practical cases exemplifying specific situations in which the said decision has been taken into consideration by the Portuguese State.

Finally, it is considered that Portuguese law is sufficient and balanced in terms of its provisions regarding the limitations of patent rights and it could thus serve as the "basis", or at least as a "good example", for a possible harmonisation, even though some of the limitations provided under Portuguese law are naturally already the result of harmonisation within the field of Community/ European Union law.

Résumé

La protection de la santé publique est l'une des questions les plus pertinentes et pressantes dans tout le monde.

Le „Système des Brevets", et dans le cas de la présente question les brevets chimio-pharmaceutiques, promeuvent l'innovation scientifique et technologique et, en conséquence, il y a eu d'importants progrès dans le traitement de maladies et des conditions générales de santé de la population.

Bien qu'ils puissant naturellement être compatibles, ce qui est en discussion ici, c'est la question à deux facettes de la protection de la santé publique et du „Système des Brevets", en particulier la façon idéale de les faire fonctionner ensemble.

Il s'agit d'une question complexe, qui porte sur de multiples aspects, l'une des principales inquiétudes concernant la capacité de fabrication/production et la commercialisation/distribution de médicaments (brevetés), surtout pendant les périodes d'épidémies ou de pandémies.

Afin de résoudre le problème décrit ci-dessus et de contribuer à la recherche, le „Système des Brevets" prévoit des limitations aux droits conférés par les brevets.

Cette question traitera de quelques-unes de ces limitations, notamment du point de vue de „l'accès" aux brevets chimio-pharmaceutiques et biotechnologiques par les tiers.

La loi portugaise prévoit la plupart des limitations normales aux droits conférés par les brevets, c'est-à-dire l'exception d'utilisation de recherche et d'expérimentation (article 102, paragraphe c) du Code de la Propriété Industrielle portugais), l'exception Bolar (mêmes article et paragraphe), l'importation parallèle (le CPI prévoit l'épuisement communautaire des droits, mais non pas l'épuisement international), l'exception de prescription individuelle (article 102, paragraphe b) du CPI), la licence obligatoire (article 107 du CPI) et l'expropriation (article 105 du CPI).

L'article 31 bis TRIPS, pourtant, n'a pas encore été ratifié au Portugal et il n'existe aucun autre instrument législatif en vue d'appliquer la décision WTO du 30 août 2003. De toute façon, cette

décision peut naturellement être appliquée au Portugal, bien qu'il n'existe pas de cas pratiques permettant d'exemplifier des situations concrètes où ladite décision ait été considérée par l'État portugais.

Finalement, la loi portugaise est jugée suffisante et équilibrée par rapport aux dispositions concernant les limitations aux droits conférés par les brevets et donc elle pourrait server de „base", ou au moins comme un „bon exemple" pour une éventuelle harmonisation, malgré le fait que certaines des limitations prévues par la loi portugaise résultent déjà naturellement d'une harmonisation dans le cadre du droit communautaire/de l'Union Européenne.

Zusammenfassung

Der Schutz der öffentlichen Gesundheitspflege ist eines der wichtigsten und dringensten Themen in der heutigen Welt.

Das "Patentsystem" – oder, was das gegenwärtige Thema angeht, die chemischen und pharmazeutischen Patenten – fördert die wissenschaftliche und technologische Innovation, was als Folge zu signifikanten Fortschritte bei der Behandlung von Krankheiten und den Gesundheitszustand der Bevölkerung beigetragen hat.

Obwohl beide offensichtlich vereinbar sein können wird heutzutage die Beziehung zwischen öffentliche Gesundheitspflege und "Patentsystem", d.h. die ideale Form ihrer Vereinbarkeit, Gegenstand ständiger Diskussionen.

Es handelt sich um ein komplexes Thema das zahlreiche Varianten unfasst, insbesondere gibt es Bedenken in Bezug auf die Fähigkeit der Herstellung/Erzeugung und des Handels/Verteilung von Medikamente (die Gegenstand von Patenten sind), haupsächlich im Hinblick auf mögliche zukünftige Epidemien und Pandemien.

Im "Patentsystem" werden Einschränkungen der Patentrechte vorgesehen, nicht nur um das vorgehende Problem zu lösen, als auch um zur Forschung der Produkte beizutragen.

Einige dieser Einschränkungen werden hier erwähnt, namentlich in Bezug auf den "Zugang" von Dritten zu chemischen, pharmazeutischen und biotechnologischen Patenten.

Das portugiesische Recht umfasst die meisten der normalen Einschränkungen der Patentrechte, namentlich Forschung und Versuchszwecken-Ausnahme (Artikel 102, Absatz c) des portugiesischen Patentgesetz), Bolar-Ausnahme (derselbe Artikel und Absatz), Parallelimport (im portugiesischen Patentgesetz ist die gemeinschaftliche aber nicht die internationale Erschöpfung vorgesehen), individuelle Verschreibung-Ausnahme (Artikel 102, Absatz b) des portugiesischen Patentgesetz), Zwangslizenz (Artikel 107 des Patentgesetz) und Enteignung (Artikel 105 des Patentgesetz).

Zu erwähnen ist auch dass Artikel 31 bis) TRIPS noch nicht ratifiziert worden ist in Portugal, und ebenfalls dass es keine gesetzgebende Instrumente verfügbar sind zur Ausführung der Entschliessung des WTO vom 30. August 2003. Auf jeden Fall, kann diese Entschliessung sebstverständig in Portugal angewendet werden, obwohl man keine praktische Fälle kennt die als Beispiel dienen können in Bezug auf konkreter Umstände wo die Entschliessung vom portugiesischen Staat angenommen worden ist.

Schliesslich muss man hervorheben dass das portugiesische Recht sowohl genügend als auch ausgeglichen ist im Voraussehen der Einschränkungen der Patentrechte und deshalb als "Grundlage" oder mindestens als "ein gutes Beispiel" dienen könnte für eine eventuelle Harmonisierung, obwohl einige im portugiesischen Recht vorgesehenen Einschränkungen tatsächlich bereits von einer Harmonisierung ableiten im Rahmen des Gemeinschaftsrechts der Europäischen Gemeinschaft.