

# “Extended Protection” and Reversal of Burden of Proof in Respect of Patented Process for Obtaining New Product:

Comments on the Supreme People’s Court’s Review of Zhang Xitian Case (No. Mintizi 84/2009)

He Huaiwen

For a process patent,<sup>1</sup> the scope of protection is extended to the product obtained directly by the process (the “extended protection”), and where certain conditions are satisfied, the burden of proof is allocated otherwise.<sup>2</sup> These two rules are critical for process patents, and are explicitly set forth in the main international IP agreements, such as the Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement) and the European Patent Convention (EPC).<sup>3</sup> They are also provided for in Article 11, paragraph one, and Article 61, paragraph one, of the Chinese Patent Law as of 2008.<sup>4</sup> However, views have long been divided as to what constitutes a “product directly obtained by the patented process”<sup>5</sup> within the meaning of Article 11, paragraph one, of the Patent Law, and as to what constitutes a “new product” and “identical product” within the meaning of Article 61, paragraph one, of the Patent Law.<sup>6</sup> The Supreme People’s Court’s Interpretation of Several Issues Relating to Application of Law to Trial of Cases of Dispute Arising from Patent Right Infringement (No. Fashi 21/2009) (the Patent Judicial Interpretation)<sup>7</sup> seeks to provide a harmonised solution, and this effort must be understood in the light of the Supreme People’s Court’s Review of Zhang Xitian case in September 2010. This paper is intended to examine the two aspects of the patent protection for a process by looking into the Zhang Xitian case<sup>8</sup>. The writer will first summarise the pertinent findings and holdings of the case, and then examine the two aspects respectively.

## I. Summary of Zhang Xitian Case

Levamlodipine is a new-generation antihypertensive drug of Amlodipine. Amlodipine, a chiral drug, is a racemate in the form of equal amount of laevo isomer (S-enantiomers) and dextroisomer (R-enantiomers). R-amlodipine almost has no antihypertensive effect; it causes such side effects as headache, dizziness, peripheral edema, and facial flushing. In contrast, S-amlodipine is the active antihypertensive agent of amlodipine. S-amlodipine has its antihypertensive effect 1,000 times that of R-amlodipine, and twice that of recemic.<sup>9</sup> S-amlodipine, however, cannot be directly used as an antihypertensive drug. Only after it is turned into lamlodipine maleate and benzenesulfonic acid levamlodipine through salt process with Maleic benzenesulfonic acid, etc, is it suitable for clinic use.

In 2000, Zhang Xitian filed an application for a patent for the invention of resolution of amlodipine antipode (hereafter “the patent in suit”), disclosing a process for making S-amlodipine, and was granted the patent (00102701.8) in 2003. Claim 1 of said patent goes as follows:

“A process for isolating (R)-(+)- and (S)-(-)-isomers of amlodipine from the mixture, characterized in that it comprises the following reactions, namely in the chiral auxiliaries dimethyl sulfoxide six (DMSO-d<sub>6</sub>) or in the organism solvents containing DMSO-d<sub>6</sub>, the mixture of isomers reacts with chiral reagent D- or L-tartaric acid, combining with (S) of a DM-

SO-d6-(-)-D of amlodipine-tartrate, or combining (R) of a DMSO-d6-(+)-L of amlodipine-tartrate and respectively precipitates, wherein the molar ratio of amlodipine and tartaric acid is proximately equal to 0.25.”

In 2005, Zhang Xitian sued in the Changchun Intermediate Court, Jilin Province, accusing the following firms for infringement: the Zhongqi Pharmaceutical Technology (Shijiazhuang) Co., Ltd. of the Shiyao Group (“Zhongqi”), which researched and developed the new drug of S-amlodipine maleate and S-amlodipine maleate tablets; the Huasheng Pharmaceutical Co., Ltd. of the Shijiazhuang Pharmaceutical Group (“Huasheng”), which made the S-amlodipine maleate (the raw material drug); the Ouyi Pharmaceutical Co., Ltd. of the Shijiazhuang Pharmaceutical Group (hereafter “Ouyi”), which made the S-amlodipine maleate tablets (the final products by the commodity name “Xuanping”); and Jilin Province Yushuntong Pharmaceutical Industry (“Yushantang”), which marketed S-amlodipine maleate tablets.

The first-instance judgment ordered Zhongqi, Huasheng and Ouyi to cease and desist from infringement. These companies were not satisfied with the judgment and appealed to the Jilin Province Higher Court. The appeal was rejected. In 2009, the Supreme People’s Court decided to review the case.<sup>10</sup>

Among the five issues reviewed by the Supreme People’s Court, extended protection for process patents and distribution of burden of proof are pertinent for the purpose of this paper. According to the judgment, where the plaintiff requested the court to reverse the burden of proof under Article 57, paragraph two, of the Patent Law as of 2000,<sup>11</sup> it was necessary for the plaintiff to “prove that the product made by the patented process was a new product, and the product made by the accused infringers was identical with the product made by the patented process”. In this connection, “new product” should be determined by looking at “the product directly obtained by the patented process”. The Court held that “the product directly obtained by the patented process” refers to an “original product obtained by using the patented process, to the exclusion of any subsequent product or products obtained through further processing the original product”.

Accordingly, the Supreme People’s Court found that according to claim 1 of the patent in suit, the “product directly obtained” was the “combining with (S) of a DMSO-d6-(-)-D of amlodipine-tartrate, or combining (R) of a DMSO-d6-(+)-L of amlodipine-tartrate”. It should be noted that the for-

mer is the intermediary substance for making S-amlodipine, not the S-amlodipine itself. On the ground that the intermediary substance was not known to the public in the world before the filing date of the patent in suit, the Supreme People’s Court ruled that it constituted a new product within the meaning of Article 57, paragraph two, of the Patent Law as of 2000.

However, the Supreme People’s Court refused to reverse the burden of proof. According to the judgment, while Zhang Xitian presented evidence that Huasheng and Ouyi had made S-amlodipine maleate and S-amlodipine maleate tablets, and that S-amlodipine maleate was made from S-amlodipine, it failed to present evidence to show that Huasheng and Ouyi had also made the intermediary substance by combining with (S) of a DMSO-d6-(-)-D of amlodipine-tartrate when making S-amlodipine maleate and S-amlodipine maleate tablets. Therefore, the Court ruled that the evidence presented was not sufficient to prove that the products made by the two defendants were identical with those directly obtained by the patented process.

As for “extended protection”, the Supreme People’s Court took the view that under Article 11 of the Patent Law as of 2000, the protection accorded to process patents was extended only to a product that had been directly obtained by said patented process, namely, an original product obtained by the patented process, but not to a subsequent product obtained through further processing said original product. In the present case, without further processing said product directly obtained according to claim 1, it was impossible to obtain the S-amlodipine maleate, S-amlodipine maleate tablets and S-amlodipine made by Huasheng and Ouyi. Accordingly, the defendants’ products were not “those directly obtained by the patented process” in the meaning of the Article 11 of the Patent Law.

## II. “Extended protection”

The reason that patent protection should be extended to the product obtained directly by the process is entirely out of practical economic consideration.<sup>12</sup> For the first place, the value of a process patent could only be realised by putting the product made from said process on the market. Second, while the products made through the process are readily available in the marketplace, it is often practically impossible for a process patentee to gain direct evidence showing a defendant’s actual use of the patented process when enforc-

ing the patent. Third, without extended protection, a process patent can be easily and legitimately avoided. For example, a third party may make a product through said process in a country where the process is not patented and protected, and then imports the products obtained to the countries where the process is under patent protection, so as to make money in a wholly lawful manner.

The rule for “extended protection” for a process patent is an exception to the general principle that “the extent of protection of a patent shall be determined by the claims”<sup>13</sup>. Since the claims of a process patent only define the technical features of the process claimed, not those of the product directly obtained through the patented process, the scope of “extended protection” thus turns on the reach of the term of “directly obtained by the patented process”. This is especially the case where a product directly obtained by a patented process may become a final product only through further processing.

In Zhang Xitian case, the Supreme People’s Court held that a “product directly obtained by a patented process” was an “original product directly obtained through the patented process”, and the protection accorded to a process patent “should not be extended to a subsequent product obtained through further processing said original product”. This holding of “extended protection” is narrower than that embraced by the Patent Judicial Interpretation. The Article 13, paragraph one, thereof provides that an original product obtained through a patented process is a product directly obtained by a patented process falling within the meaning of Article 11 of the Patent Law, and does not suggest that the two are equal.

The above holding seems to follow the UK Manual of Patent Practice.<sup>14</sup> Under Article 61, paragraph one (c), of the UK Patent Act as of 1977, the protection of a process patent shall extend to a product obtained directly by means of that process. The UK Manual of Patent Practice claims that, in *Pioneer v. Warner*<sup>15</sup>, Justice Aldous of the first-instance court construed “directly” within the meaning of Article 61 paragraph one (c) of the UK Patent Act as “without intermediary”, and this view was supported by Justice Nourse of the court of appeal.<sup>16</sup> But it must be noted that it is also pointed out in the Manual that “thus to infringe, a product must be the direct product of the claimed process and not a product resulting from further material and important steps”.<sup>17</sup> More importantly, the *Pioneer v. Warner* in fact takes “the loss of identity test”,<sup>18</sup> like major members of the EPC, such as Germany.<sup>19</sup>

According to the “loss of identity test”, unless subsequent steps substantially change the identity of the product obtained directly by means of the patented process, such product does not necessarily stop to be the product obtained “directly” by means of the patented process merely because subsequent processing is involved.<sup>20</sup> Otherwise, a third party can simply avoid the extended protection of the process patent by adding some minor subsequent steps. Moreover, in *Halliburton Energy Services Inc. v. Smith International (North Sea) Ltd.*,<sup>21</sup> the judge even concluded that when a product derived from a patented process is an input for subsequent processes, the protection of a process patent may “go as far as a product by process claim might go, but no further”.<sup>22</sup>

The loss of identity test, a mainstream view of the European nations on “extended protection”,<sup>23</sup> is substantially similar to the position of the US Patent Act, though the latter approaches this issue in a negative manner. It is provided in 35 U.S.C. § 271(g) that “a product which is made by a patented process will...not be considered to be so made after (1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product.”<sup>24</sup>

The “loss of identity test” is by no means flawless, and its application to individual cases is far from being simple and direct.<sup>25</sup> If there are sufficient reasons, we could avert it and take a test that make more sense both in terms of law and the Chinese market. The Supreme People’s Court might have good grounds to hold that “product directly obtained by a process patent” is equal to “product originally obtained through the patented process” in the light of the totality of circumstances of the Zhang Xitian case. But if this holding is to be applied as a rule of law, careful consideration must be taken of the possible social and economic impact.

First, this standard has considerable impact on patent protection for processes for making pharmaceuticals. Pharmaceuticals made by a patented process typically must be further processed before it can be put on the market. Simple subsequent process includes, for example, grinding, adding non-active ingredients to form a particular dosage; or some simple chemical reactions, such as esterification or salt process. Complicated subsequent processes may include chemical reactions to change molecular structure of some active ingredients, for example, change the location of a substituent or add a new substituent. Subsequent processes may contribute much less to the value of the final marketed

pharmaceutical product than the patented process, especially where a product obtained by a patented process is a new one.<sup>26</sup> Therefore, from the perspective of the Patent Law, if any subsequent process can destroy the “directness” between the process for making a pharmaceutical product and the pharmaceutical product so obtained, third parties could easily avoid the patented process by adding insignificant steps, rendering the patent for the process practically meaningless.

Moreover and importantly, this standard would also make it easy for a third party to avoid a patent for a process granted in China. He only needs to use the process in a country where it is not patented and protected by adding minor subsequent processes, and then legitimately imports the product so made into China. As a result, China would lose not only the investment directly related to the exploitation of the process patent, but also job opportunities. These unexpected repercussions are not good news for China, for it is still under the shadow of the financial crises, and under the efforts to make it a nation of innovation.

### III. Distribution of Burden of Proof

In a process patent infringement lawsuit, when Plaintiff presents evidence meeting certain requirements, the burden of proof may be reversed, that is, it is for the defendant to be under the burden to prove that he has made identical products through a process different from the patented process in suit, under the pain of the presumption that he actually used the patent in suit. This rule is put in place to address the quandary a patentee typically faces when enforcing a process patent: the rightholder is usually unable to have a legitimate access to the site to collect direct evidence for the alleged infringer’s actual use of the patented process because production and trade secrets are under legal protection. It is more difficult to collect evidence when the patentee of a process patent wants to enforce the patent against one who imports, without permission, a product obtained directly by a patented process, as the product is made in another country. It is fair to say that the reversal of burden of proof is also a sort of “extended protection”, but in terms of procedure law.

This reversal of burden of proof is an exception to the general evidence rule that those who claim relief must carry the burden to prove the claim. Article 61, paragraph one, of the current Patent Law (the same provision as Article 57,

paragraph two, of the Patent Law as of 2000) provides “in infringement disputes relates to a invention patent for a process whereby a new product is obtained, any entity or individual manufacturing the identical product shall produce evidence to prove that a different process was used in manufacturing the product.” In the Zhang Xitian case, the Supreme People’s Court clearly pointed out that “to invoke Article 57, paragraph two, of the Patent Law as of 2000<sup>27</sup>, the rightholder should first show that the product made by the patented process is a new product, and that the product the accused infringer has made is identical with that new product”. That is, when the rightholder proves the two circumstances, the court will make a rebuttable factual presumption that the defendant actually used the patented process.

In the light of the patent law, when these two requirements are met, the patentee’s interest is superior to that of the alleged infringer’s interest of protecting his production and trade secret. In this event, it is more likely for the defendant to know about the new product through the patent, and it is thus made possible for him to find another process to make the new product. Without the disclosure of the patent for the process for making the new product, it is less likely that the defendant could ever sell a product identical with the new one. Without entering the site, it is often impossible to determine whether the defendant used a secret process different from a patented process or take this as a pretext. However, in this situation, it is more likely that the defendant used the patented process rather than an independently developed different process. Within a certain period of time after a new product comes into being, there is only one known process to make it. If, within this period, a manufacturer refuses, without good reasons, to prove that he used a process different from the patented process to make the identical product, common sense compels one to conclude that the manufacturer used the patented process. Of course, when a reasonable period of time has passed after a new product comes into being, it is much more possible for a third party to come up with a process different from the patented process. In this event, to draw the above factual presumption may not remain fair and equitable.

To apply Article 61, paragraph one, of the current Patent Law, the key lies in the determination of whether there is a “new product” and “identical product”. In so doing, the two legal terms must be interpreted in the spirit of the purpose of reversal of burden of proof. That is to allow judges to determine with sufficient assurance that the defendant did use the

patented process without authorisation. In addition, these two terms should also be construed in a fair and equitable fashion in order to conform with the essential requirement of the TRIPS Agreement relating to IP civil procedure.<sup>28</sup>

There were divergent views as to what constitutes a “new product” under the Chinese Patent Law. The Beijing Higher Court provided in Article 122 of the Opinions on Several Issues Relating to Patent Infringement Adjudication (Tentative) (No. Jinggao fafa 229/2001) that “the ‘new product’ means a product that is manufactured for the first time in this country and which is obviously different, in composition, structure or quality, performance or function, from the existing product of the same class before the date of filing of the patent.” However, the Detailed Explanation of the New Patent Law (2001) approaches this legal term in a different way. In its view, the term “new” is different from “novelty”, and a product is deemed to be “new” so long as it is not seen in the market in China before the filing date of the patent for the purpose to shift the burden of proof to the defendant.<sup>29</sup> And yet in its Reply made in October 2008, the Supreme People’s Court took the view that the “new product” shall refer to a product that is not made publically available in China and in foreign countries before the filing date of the patent in suit and is not identical with, nor equivalent to, an existing product.

The Patent Judicial Interpretation as of 2009, which is currently in force, takes an approach to this legal term in two different points from the above. First, it no longer stresses “product”, but emphasise the technical solution of the product or the process to make it. On the other hand, its wording corresponds to the “prior art” as provided for in Article 22 of the current Patent Law.<sup>30</sup> Article 17 thereof reads as follows: “where the technical solution of the product or the process to make it is unknown to the public in this and other countries as of the filing date of the application for the patent, the courts shall determine that such product is a ‘new product’ within the meaning of the Article 61, paragraph one, of the Patent Law as of 2008.”

In Zhang Xitian case, the Supreme People’s Court, on the one hand, followed the Article 17. In the judgment, the Court stressed that a “new product” is “new” in the light of the filing date on a worldwide basis, thus reject the holding of the first-instance and second-instance courts that a “new product” turns on whether it was marketed in China. Sure, this holding is in the interest of the patentee, and is adopted by quite a few countries.<sup>31</sup> However, a simple fact should not

be disregarded: as time passes by, it is more possible, especially approaching the expiry of a patent, that other processes for making the identical products will have been developed.<sup>32</sup> In this event, to presume that the defendant used the patented process without exception may be contrary to the fair and equitable principles of the civil procedure law and even in violation of the TRIPS Agreement.<sup>33</sup> The case may call for, as it is required in Article 34, paragraph three, of the TRIPS Agreement, the court to consider the defendant’s legitimate interests in protecting his production and trade secret.

On the other hand, in this case, the Supreme People’s Court imported a narrower meaning into the term “new product” than that in Article 17. The Court held that “whether a new product is made through a patented process should be determined on the basis of the product directly obtained by the patented process”, and “the product directly obtained by the patented process” refers to “the original product obtained through the patented process, and does not include any subsequent product obtained by further processing of the original product”. In other words, the so-called “new product” within the meaning of Article 61 means an “original product” obtained by a process patent which was unknown to the public in China and elsewhere before the filing date. In so doing, the Supreme People’s Court did not identify the features distinguishing “new product” from the prior art, namely “the technical solution of the product or the process to make it” as of the filing date as required by Article 17 of the Patent Judicial Interpretation as of 2009. Rather, the Court found the “new product” by inquiring whether an “original product” obtained from the patented process is “new” or not. However, a subsequent product obtained by further processing the “original product” may retain all the technical features of a “new product”: the mark of actual use of the patented process. In this event, it could hardly be said in terms of evidence that the “directness” of the product at issue with the proof of actual use of the patented process is destroyed by virtue of the subsequent processing.

To delimit “new product” on the basis of “original product” not only directly narrows the coverage of this legal term, but also indirectly narrows the scope of “using a process patent”. Under Article 13, paragraph two, of the Patent Judicial Interpretation, further processing an original product to obtain a subsequent product constitutes “use” of the product directly obtained through the patented process producing the original product. This sort of “use” does not fall within

the scope of Article 61 of the current Patent Law, which only requires the defendant to present evidence to show that “his process for manufacturing its product is different from the patented process”, but does not require him to provide evidence to prove that the intermediary product it used to make his product is different from that directly obtained by the patented process. Thus, the burden of proof may not be reversed even if the further processing, or use of the product directly obtained, does not destroy the mark of the patented process. It is evident that the holding of the Court in this case tends to substantially curtail the reach of the Article 61, paragraph one, of the current Patent Law.

While the above analysis shows that distinguishing technical features are of legal significance in determining “new product”, it does not mean that they should be the “only” test as to whether the defendant has made the “product identical with the new product”. For example, there may be cases where two substances differ in chemical structure and according to the law of the nature, it is impossible for the two substances to be obtained from the same raw material and by the same steps. In this event, even though the two substances are of the same nature in application, they should not be held to be identical products for the purpose to shift the burden of proof from the plaintiff to the defendant.<sup>34</sup>

Moreover, even if the defendant provides evidence to show that there are the differences in respect of raw material or some steps from the patented process so long as an alleged infringer makes the “identical product”, reversal of burden of proof may still be a just practice. It should be noted that Article 61, paragraph one, of the current Patent Law concerns itself with “infringement disputes over an invention patent for a process whereby a new product is obtained”, not limiting itself to literal infringement. As this Article is put in place to effectively protect patents for processes for making new products by facilitating enforcement of the patents, there is no reason why it should not be applied to infringement by equivalents.<sup>35</sup> Accordingly, if an alleged infringer makes “identical product”, the burden of proof may be shifted to the defendant, who may rebut the presumption that he made the product by a process identical with, or equivalent to, the patented one.

In the Zhang Xitian case, the Court found a “new product” on the basis of “original product” obtained by the patented process. In so doing, the reasoning looks more in support of a finding of a new “process”, rather than a “product”. According to the judgment, because the patent

95192238.6 (named as “invention of amlodipine of diastereomer of its antipode separated by tartaric acid”) filed by Pfizer in 1995 and the patent in suit filed in 2000 disclose different chiral auxiliaries--DMSO and DMSO-d6 respectively--to resolve amlodipine, and thus different intermediary substances were prepared, the Pfizer’s patent thus did not disclose the product obtained directly by the patented process in suit, and was not sufficient to rebut that the patented process in suit produce the “new product” within the meaning of Article 57 of the Patent Law as of 2000. However, the value of the two intermediary substances resides in the structure of the antihypertensive active molecule, namely S-amlodipine in isolation; and the fact that they are prepared via two different chiral auxiliary only showed that the patented process in suit had new technical features compared to the Pfizer’s patented process.

Anyway, the Supreme People’s Court found, in the Zhang Xitian case, that the patent in suit was one for “a process for making new product”.<sup>36</sup> But the Court refused to shift the burden of proof to the defendant on the ground that the plaintiff did not prove that Huasheng and Ouyi made the “intermediary substance” of combining with (S) of a DMSO-d6-(-)-D of amlodipine-tartrate when making S-amlodipine maleate and S-amlodipine maleate tablets, i.e., the product obtained directly through the patented process in suit, thus failing to show that the defendant made the “identical product” with the new product. This suggests that the Supreme People’s Court refrained from reversing the burden of proof neither because the final pharmaceutical made and marketed by the defendants could not be made on the basis of the original product through normal chemical reaction (say, salt process), nor because the final product did not contain the chemical structural features of the original product. The underlying reason might well be that, according to Article 13, paragraph two, of the Patent Judicial Interpretation, the defendant’s act of further processing said original product and obtaining the subsequent product is an act of using product obtained directly by the patented process, not an act of using the patented process within the meaning of Article 57 of the Patent Law as of 2000.

The totality of the circumstances of the Zhang Xitian case may justify the Supreme People’s Court’s holding that “new product” and “identical product” within the meaning of Article 61 of the current Patent Law (or Article 57 of the former Patent Law) should be interpreted on the basis of “original product”. However, this holding should not be taken as a



rule of law of general application. When a “new product” made by a patented process is not an end product, but an “intermediary product”, requiring a plaintiff to prove that the defendant produced the same “intermediary product” in his production to meet the condition of “identical product” may be equal to requiring him to enter the defendant’s production site to collect evidence of “intermediary product”. But for this undue and unrealistic evidence collecting burden, reversal of burden of proof is put in place. Moreover, this reversal of burden of proof would be rendered toothless when a third party would avoid the harshness thereof by simply adding steps of minor importance to the steps of the patented process.

In conclusion, as for the protection of process patents, what matters is not whether a product is an “original” one obtained through the patented process, but whether a “direct” one. It should be noted that the concept of “product” in the light of patent law refers to a set of technical features, not a particular physical existence.<sup>37</sup> As a result, a “new product” should be identified on the basis of its technical features. Similarly, when identifying whether a defendant makes a product “identical” with the “new product”, the basis should be the technical features. Sure, a product must change with processes subsequent to the patented process and stop to be an “original product” obtained through the patented process. But the particular technical features may remain unchanged, and the product containing those features may still have the “directness” to the patented process in terms of proof of actual use of the patented process by the defendant.

## Conclusion

Since the Patent Judicial Interpretation as of 2009 came into effect, the Zhang Xitian case is undoubtedly one in which the most important judgment has been made regarding process patents. In this case, the Supreme People’s Court held that a “product directly obtained through the patented process” is equal to an “original product” obtained through the patented process. Building on this holding, the Court delimited the scope of the “extended protection” accorded to a process patent and the conditions precedent for reversal of burden of proof. The analysis in this paper shows that the legal meaning of the term “directly obtained” is far from being that “direct” and straightforward, especially when an original product obtained through the patented pro-

cess is an input into subsequent processes, rather than an “end product”. The reach of “directly obtained” bears significantly upon a process patent, as it determines the scope of the “extended protection” of process patents in terms of both substantive and procedural laws. In this respect, the holding of the Zhang Xitian case falls short to provide a satisfactory and conclusive answer, but only reveals the deeper issues that call for research and clarification. ■

The author: IP law faculty member of the Guanghua Law School of Zhejiang University, Email: zjuhwh@gmail.com

<sup>1</sup> For the purposes of this paper, only processes that result in products are to be considered. A “process” is typically a technical solution consisting of a series of steps, and the result of a process may be a product. Processes may be of a chemical nature, leading to chemical compounds, or may belong to other fields of technology. Several different processes may be used, one after another, in order to produce a product; therefore, a “product” may also be an intermediate form of a product. Moreover, processes may effect the transformation or finishing of existing products (for example, the painting, drying, etc., of a product). In addition to processes that produce products, there also exist processes that have other technical effects, such as creation of energy, heat, sounds, etc., the analysis of substances or the measuring of temperature, etc. See WIPO document HL/CE/III 2 Supp. 4, of November 27, 1986. See also the Detailed Explanation of the Patent Law by the Legal Affairs Department of the State Intellectual Property Office, the Publishing House of Intellectual Property, 200, Pp.70-71.

<sup>2</sup> See, e.g., WIPO document HL/CE/III 2 Supp. 4, of November 27, 1986, at: [http://www.wipo.int/mdocsarchives/HL\\_CE\\_III\\_87/HL\\_CE\\_III\\_2%20Supp%204\\_E.pdf](http://www.wipo.int/mdocsarchives/HL_CE_III_87/HL_CE_III_2%20Supp%204_E.pdf).

<sup>3</sup> See, e.g., Article 28 (1) and 34 TRIPS Agreement; Article 64 (2) EPC and Article 25 (c) of the Community Patent Convention (CPC). It should be noted that Article 5 of the Paris Convention for the Protection of Industrial Property only provides that the owner of a process patent enjoys right in the imported products obtained by his process patent under the law of the country of importation, without providing for “extended protection” and distribution of burden of proof in infringement disputes.

<sup>4</sup> See also Article 11 (extended protection) and Article 57 (distribution of burden of proof) of the Chinese Patent Law as of 2000; Article 11 (extended protection) and Article 60, paragraph two, (distribution of burden of proof) of the Chinese Patent Law as of 1992.

<sup>5</sup> Article 11, paragraph one, of the Chinese Patent Law as of 2008 provides: “after the grant of the patent right for an invention or utility model, except otherwise provided for in this Law, no entity or individual may, without the authorisation of the patentee, for production or busi-

ness purposes, exploit the patent, that is, make, use, offer to sell, sell or import the patented product, or use the patented process, and use, offer to sell, sell or import the product directly obtained by the patented process”.

<sup>6</sup> Article 61, paragraph one, of the Chinese Patent Law as of 2008 provides: “in infringement disputes over an invention patent for a process whereby a new product is obtained, any entity or individual manufacturing the identical product shall come forward with evidence to prove that a different process was used to manufacture the product.”

<sup>7</sup> Adopted at the 1480th meeting of the Adjudication Board of the Supreme People’s Court on 21 December 2009 and went into force on 1 January 2010.

<sup>8</sup> Zhang Xitian v. Ouyi Pharmaceutical Industry Co., Ltd. at al. (the Supreme People’s Court’s Civil Judgment No. Mintizi 84/2009) (retrieved on 9 September 2010). See also Zhang Xitian v. Ouyi Pharmaceutical Industry Co., Ltd. at al. (the Jilin Province Changchun City Intermediate Court’s Civil Judgment No. Changminsanchuzi 36/2005; and the Jilin Province Higher Court’s Civil Judgment No. Jiminsanzhongzi 146/2006.

<sup>9</sup> Guo Yifang, Huang Zhongyi and Hu Dayi, “Chinese Experts’ Consensus on Clinic Application of benzenesulfonic of S-amlodipine at [http://www.chinesefms.com/doc/xxg/doc\\_xxg\\_xzzn/201001/t20100130\\_41508.html](http://www.chinesefms.com/doc/xxg/doc_xxg_xzzn/201001/t20100130_41508.html).

<sup>10</sup> The Supreme People’s Court’s Civil Judgment No. Minshenzi 2/2009.

<sup>11</sup> Article 57, paragraph two, of the Chinese Patent Law as of 2000 provides: “In infringement disputes over an invention patent for a process whereby a new product is obtained, any entity or individual manufacturing the identical product shall come forward with evidence to prove that a different process was used to manufacture the product.”

<sup>12</sup> Supra note 2

<sup>13</sup> See Article 59, paragraph one, of the Chinese Patent Law as of 2008.

<sup>14</sup> See the Manual of Patent Practice (January 2011), p.4, available at: <http://www.ipso.gov.uk/practice-sec-060.pdf>.

<sup>15</sup> See Pioneer Electronics Capital Inc. and another v Warner Music Manufacturing Europe GmbH and another [1995] R.P.C. 487.

<sup>16</sup> See Pioneer Electronics Capital Inc. and another v Warner Music Manufacturing Europe GmbH and another [1997] R.P.C. 757.

<sup>17</sup> “Thus to infringe, a product must be the direct product of the claimed process and not a product resulting from further material and important steps”. Supra note 14.

<sup>18</sup> Supra note 16.

<sup>19</sup> See, e.g., Pioneer Unmittelbares Verfahrenserzeugnis, Case No. 2U148/76, [1979] GRUR 743 (Germany, Düsseldorf Oberlandesgericht, 15 September 1977); Pfizer (Doxycycline) NJ 1984/32 (Netherlands, Hoge Raad, 10 June 1983); Merz & Co. v. Federal Office of Intellectual Property, [1994] the Bundesgericht (Federal Supreme People’s Court)

and Farbwerke Hoechst v. Carlo Erba SpA, [1972] SMGRUR 57 (Switzerland, Zurich Commercial Court).

<sup>20</sup> Ibid. See also Pioneer Unmittelbares Verfahrenserzeugnis, Case No. 2U148/76, [1979] GRUR 743 (Germany, Düsseldorf Oberlandesgericht, 15 September 1977).

<sup>21</sup> [2006] RPC 2.

<sup>22</sup> See id para.97 (“I should add that the European Patent Office’s great reluctance to grant ‘product by process’ claims on the unchallengeable logical basis that novelty cannot be conferred on an old article by making it according to a new process encourages me to give section 60(1) (c) an interpretation that goes as far as a product by process claim might go, but no further”).

<sup>23</sup> In Pioneer v. Warner, the court of appeal referred to patent cases of the main European countries, such as Germany, Switzerland, and the Netherlands, believing that the “loss of identity test” is the law standard for them to determine the “extended protection” of process patent. See Pioneer Electronics Capital Inc. at al. v Warner Music Manufacturing Europe GmbH and another [1997] R.P.C. 757.

<sup>24</sup> 35 U.S.C. § 271(g) (“Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent . . . . A product which is made by a patented process will, for the purposes of this title, not be considered to be so made after (1) it is materially changed by subsequent processes; or (2) it becomes a trivial and nonessential component of another product”).

<sup>25</sup> See, e.g., Pioneer Electronics Capital Inc. and another v. Warner Music Manufacturing Europe GmbH and another [1997] R.P.C. 757. The case involved a patent for the process for making CD metal father. The defendant imported the CDs in suit and sold them in the United Kingdom. The disputable issue of law was whether the CDs the defendant imported and made by the patented process were products obtained directly by means of a patented process as mentioned in Article 60, paragraph one, (c) of the UK Patent Act as of 1977. Technically, to produce CDs, it was necessary to make a metal father thereof. To make it, first a clean glass master was used as a platform to make the CDs. According to the different CD standards and production requirements, on each glass master was evenly applied PR coating of certain thickness; then laser ray recorder was duly used for exposure of the light sensitive reagent; after that developer was used to erode the light sensitive reagent to form the needed information ditches and rills. The CDs were then sputtered to form the initial; the initial was electrically casted into metal father. The father could not be directly used as a stamper for injection molding. Rather, it was then turned into mother through electric plating in an



electrolytic cell. Through the same steps again, the mother forms the son identical with the metal father in structure. After that, a central hole and edge were punched in the son, the back of it was polished, and the stamper was formed. The stamper was put in the mold or die, and optipolycarbonate was injected into the convex part of the mold to reproduce the information ditches and rills of the stamper, thus a transparent master was made. Then the CDs were made after the steps of dye coating, sputtering, bonding and printing. In the case, the court, making use of the loss of identity test, found the final product, the CDs, the defendant made, and the father, the mother and the son were not identical products; they no longer possess the identity after the processing steps, nor could they be played as the final CDs. While the father, the mother and the son and the final CDs contained the same information, or said patented process determined the essential characteristics of the CDs, the court of appeal concluded that the essential characteristics were not a legal standard independent from the loss of identity test, and could be used to determine “products obtained directly by means of a patented process”.

<sup>26</sup> See Amiram Benyamini, Patent infringement in the European Community, in IIC Studies Vol.13 (1993) (“The words ‘obtained directly’ were interpreted in Germany as covering, in addition to the original product prepared according to the process, any product obtained by further processing or use of the original product, if the value or main characteristics of the end product were largely determined by the use of the process or original product.”).

<sup>27</sup> Supra Note 11.

<sup>28</sup> See generally Joseph Straus, Reversal of the Burden of Proof, the Principle of “fair and equitable procedures” and preliminary injunctions under the TRIPS Agreement, *The Journal of World Intellectual Property*, 2005, Vol.3, Pp.807-823.

<sup>29</sup> The Legal Affairs Department of the SIPO, Detailed Explanation of the New Patent Law, the Publishing House of Intellectual Property, 2001, P.298.

<sup>30</sup> Article 22, paragraph 5, of the Chinese Patent Law as of 2008 provides: “the existing technologies mentioned in this Law shall refer to those known to the public in China and in foreign countries before the date of filing.”

<sup>31</sup> See, e.g., *Merck and Co Inc v Pharmaforte Singapore Pte Ltd* [2002] 3SLR 515.

<sup>32</sup> See Resource Book on the TRIPS Agreement and Development (2005), p.500, available at: [http://www.iprsonline.org/unctadictsd/docs/RB2.5\\_Patents\\_2.5.9\\_update.pdf](http://www.iprsonline.org/unctadictsd/docs/RB2.5_Patents_2.5.9_update.pdf).

<sup>33</sup> See Article 41, paragraph two, of the TRIPS Agreement: Procedures concerning the enforcement of intellectual property rights shall be fair and equitable; Article 42 of the TRIPS Agreement: Members shall make

available to rightholders civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

<sup>34</sup> See Federal Supreme People’s Court (Bundesgerichtshof) 25.06.1976 Case: X ZR 4/75 “Alkylenediamine II” 8 IIC 350 (1977) (holding that effective protection of a process for the manufacture of a new substance can only be provided when the rule adjusting the burden of proof applies not only to cases of immediate, objective infringement, but that the rule must extend at least sufficiently wide that cases of equivalent, improved, or less advantageous use are also included).

<sup>35</sup> See id.

<sup>36</sup> In a case of dispute over process patent infringement, even if a plaintiff cannot prove the new product and the alleged infringer’s identical product, the court may fairly and duly distribute the burden of proof according to the specific circumstances of the case, taking due account of the need for the rightholder to enforce his right and legitimate interests of the defendant’s production and trade secret. Article 7 of the Supreme People’s Court’s Several Provisions Relating to Civil Procedure Evidence as of 2001 provides: “if there is no specific provision and when it is impossible to ascertain the burden of proof under the Provisions and other judicial interpretation, the courts may distribute the burden of proof according to the principles of fairness and good faith, taking into consideration of the parties’ ability to adduce evidence.” But in the Zhang Xitian case discussed in this paper, the Supreme People’s Court did not make any reference to this provision.

<sup>37</sup> See, e.g., Detailed Explanation of the New Patent Law, supra note 29 (“patented product” is a product having each and every technical feature of a claim”).