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REVERSAL OF BURDEN OF PROOF IN PATENT INFRINGEMENT PROCEEDINGS

The Curious Case of Singapore's Implementation of Article 34 of the TRIPS Agreement[1]

The TRIPS Agreement is usually associated with setting down substantive standards of protection for intellectual property rights. Yet, the TRIPS Agreement has one provision that deals with the issue of legal burden of proof in infringement proceedings. This is Art 34 which mandates that, in certain patent infringement proceedings, a particular essential element in the cause of action is presumed and it is for the defendant to rebut this presumption. This article investigates the *raison d'être* of Art 34 and reviews the Singapore implementation of Art 34 in the Patents Act 1994. It also suggests that the Singapore implementation is in need of reform.

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I. Introduction

1 Everyone in the intellectual property ("IP") community knows that the substantive nature of the IP rights granted by a World Trade Organization ("WTO") member is shaped, or even dictated, by the Agreement for Trade-related Aspects of Intellectual Property Rights[2] (the "TRIPS Agreement"). In the case of Singapore, for example, the scope of copyright protection for a type of work called "compilations" is defined in terms that are almost identical with those used in the TRIPS Agreement.[3] Another example is the step Singapore took in 1995 to repeal the ban in the Patents Act 1994[4] on the patenting of, *inter alia*, computer programs as such;[5] this repeal was regarded as necessary for Singapore to conform

1 Agreement on Trade-related Aspects of Intellectual Property Rights (15 April 1994) (entered into force 1 January 1995).
2 (15 April 1994) (entered into force 1 January 1995).
3 Compare Art 10(2) with the definition and scope of protection for "compilation" in ss 13(2) and 14(*a*) of the Singapore Copyright Act 2021 (2020 Rev Ed).
4 Act 21 of 1994.
5 This ban was found in s 13(2) of the Patents Act 1994 (Act 21 of 1994).

with the minimum standard of patent protection mandated by the TRIPS Agreement.[6]

2 What may come as a surprise to a few is the fact that the TRIPS Agreement also contains a provision that affects, not the substantive nature of an IP right, but the issue of burden of proof in an infringement action. This provision is Art 34 which has this short title: "Process Patents: Burden of Proof". The full text of Art 34 is set out later in this article. For the moment, it suffices to explain the significance of Art 34 in this way: it mandates WTO members to provide in their patent law that, in certain infringement actions involving a process patent, an essential element of the cause of action is presumed to be satisfied and it is for the defendant to rebut this presumption. For this reason, Art 34 has been described as the "reversal of burden of proof" provision in the TRIPS Agreement.[7] Clearly, Art 34 operates as an exception to the well-established rule in the law of evidence that the party who asserts a fact bears the legal burden of proving the existence of the fact.[8] What is its justification, and how did it find its way into the TRIPS Agreement? Further, how has Singapore implemented Art 34, and has the implementation been satisfactory?

3 Part II of this article aims to throw some light on the background and *raison d'être* of Art 34. Part III reviews Singapore's implementation of Art 34 in the form of s 68 of the Patents Act 1994 as well as the case law on s 68. In the author's opinion, there is need for reform to s 68 and this is covered in Part IV. The conclusion is in Part V.

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6 This reason was given at the Second Reading of the Patents (Amendment) Bill (Bill No 31/1995): see Singapore Parl Debates; Vol 65; Col 37; [1 November 1995] (Assoc Prof Ho Peng Kee, Parliamentary Secretary to the Minister for Law).

7 This is the description used in some of the literature on Art 34: see, *eg*, Joseph Straus, "Reversal of the Burden of Proof, the Principle of 'Fair and Equitable Procedures' and Preliminary Injunctions under the TRIPS Agreement" (2000) 3 *World Intellectual Property Journal* 807 and Miguel Vidal-Quadras Trias de Bes, "Process Patents on New Products and Reversal of Proof: Factors Contributing to the Interpretation of its Scope" (2002) 24(5) *European Intellectual Property Review* 237.

8 In Singapore, see s 103(1) of the Evidence Act 1893 (2020 Rev Ed): "Whoever desires any court to give judgment as to any legal right or liability, dependent on the existence of facts which the person asserts, must prove that those facts exist." This rule has been applied in the context of intellectual property infringement actions: see, *eg*, *Golden Season Pte Ltd v Kairos Singapore Holdings Pte Ltd* [2015] 2 SLR 751 at [193], where it was said that "[c]opyright infringement only arises where the act of reproduction is done without the licence of the copyright owner. … The legal burden of establishing that the act of copying was done without the licence of the copyright falls on the shoulders of the copyright owner."

II. Article 34 TRIPS Agreement: rationale and implementation

4 The reversal of burden of proof in Art 34 of the TRIPS Agreement affects only process patents. To appreciate the impact of Art 34, it would be appropriate to start with some background information about process patents.

5 A patent can be for a product or for a process. Indeed, the TRIPS Agreement mandates that patents shall be available for "any invention, *whether products or processes*, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application"[9] [emphasis added]. A patent for a product ("product patent") confers a monopoly over the product *per se*, and hence it is the product that must satisfy the three criteria (*ie*, novelty, inventive step and industrial application). On the other hand, in a patent for a process ("process patent"), it is the process which must satisfy the three patentability criteria. In cases where the patent is for a process of making a product, the focus is still on the *process* and not the resulting product: a process patent will be granted so long as the *process* satisfies the patentability criteria, even if the resulting product is not a new product.

6 The TRIPS Agreement also sets out the minimum scope of protection to be conferred by the grant of a process patent. The patentee must at least have the exclusive right to do the following acts:[10]

(a) to use the process; and

(b) to use, offer for sale, sell, or import for these purposes the product obtained directly by the process.

7 Two points should be noted about this minimum scope of protection for a process patent. First, since IP rights are territorial in nature, a process patent granted by one jurisdiction may be infringed only if the unauthorised act took place within that jurisdiction.[11]

9 Agreement on Trade-related Aspects of Intellectual Property Rights (15 April 1994) (entered into force 1 January 1995) Art 27(1). In Singapore, see s 13(1) of the Patents Act 1994 (2020 Rev Ed) defining a "patentable invention" by reference to these criteria: (a) the invention is new; (b) it involves an inventive step; and (c) it is capable of industrial application.

10 Agreement on Trade-related Aspects of Intellectual Property Rights (15 April 1994) (entered into force 1 January 1995) Art 28(1)(b). In Singapore, see ss 66(1)(*b*)– 66(1)(*c*) of the Patents Act 1994 (2020 Rev Ed).

11 For example, this territorial principle has been applied by the Singapore Court of Appeal in the context of trade mark rights: see *Burberry Ltd v Megastar Shipping Pte Ltd* [2019] 1 SLR 536 at [42].

For example, a process patent granted by Singapore is not infringed by *XYZ*'s use of the process in, say, Malaysia.[12]

8 Second, the effect of the exclusive right in para 6(b) above is to extend protection beyond the patented process to cover any product obtained directly by the process. This extended protection is particularly important in cases where the process is used outside of the jurisdiction to obtain the product and the product is then imported into the jurisdiction for use or sale. In the earlier example where *XYZ* uses the process in Malaysia, whilst such use *per se* does not infringe the process patent granted in Singapore, the patentee can nevertheless object to the sale in Singapore of products obtained directly by *XYZ*'s use of the process in Malaysia.

9 This scope of protection for a process patent seems very generous, especially when the extended protection in para 6(b) above is taken into consideration. However, when it comes to the enforcement of a process patent, the patentee often faces a unique challenge. This is because the patentee usually only has access to the defendant's product but is unable to get any information on how the defendant's product is made, specifically whether the patented process was used to make the defendant's product. Even if the defendant's product is identical with the patentee's product (the one obtained by the patented process), this fact *per se* does not prove that the defendant's product was made by the patented process; after all, there may well be other processes which can produce the same product. The challenge for the patentee is exacerbated when the defendant's product is produced overseas by a third party who is not subject to the jurisdiction of the court hearing the infringement action and hence cannot be compelled to provide the essential information. As such, if it is the patentee who bears the legal burden of proving each and every essential element in the cause of action, it would be very difficult for the patentee to make out a claim for infringement of his exclusive right in para 6(a) (which requires proof that the defendant used the patented process) or his exclusive right in para 6(b) (which requires proof *inter alia* that the defendant's product was directly obtained by the patented process).

12 In Singapore, see s 66(1) of the Patents Act 1994 (2020 Rev Ed): "… a person infringes a patent for an invention if, and only if, while the patent is in force, he does any of the following things *in Singapore* in relation to the invention …" [emphasis added].

10 During the negotiations for the TRIPS Agreement, it was this concern that prompted the EC,[13] the US[14] and Switzerland[15] to propose that, in certain circumstances, the defendant's product must be deemed to have been obtained by the patented process and to shift the burden to the defendant to rebut this presumption. The three parties proposed different circumstances which mandate the creation of this rebuttable presumption. Art 34 is the outcome of these deliberations. The full text of this article is set out below:

> *Process Patents: Burden of Proof*
>
> 1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:
>
> (a) if the product obtained by the patented process is new;
>
> (b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.
>
> 2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.
>
> 3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

13 Draft Agreement on Trade-Related Aspects of Intellectual Property Rights (29 March 1990), MTN/GNG/NG11/W/68, Art 24(4).

14 Draft Agreement on Trade-Related Aspects of Intellectual Property Rights: Communication from the United States (11 May 1990), MTN/GNG/NG11/W/70, Art 24(3).

15 Draft Amendment to the General Agreement on Tariffs and Trade on the Protection of Trade-Related Intellectual Property Rights: Communication from Switzerland, (14 May 1990), MTN/GNG/NG11/W/73, Art 232(3).

11 The circumstances mandating the obligation to create the rebuttable presumption are set out in Art 34(1).[16] These circumstances may be broken down into three conditions, namely:

(a) the patent is for a process for obtaining a product;[17]

(b) the defendant's product is identical with the product obtained by the process; and

(c) the product obtained by the process is a new product (the "New Product Scenario") or there is a substantial likelihood that the defendant's product was made by the process and the patentee has been unable through reasonable efforts to determine the process actually used to obtain the defendant's product (the "Substantial Likelihood Scenario").

12 In the third condition, the New Product Scenario and the Substantial Likelihood Scenario operate as alternatives;[18] *ie*, if the first two conditions are fulfilled, a WTO member can choose to create the rebuttable presumption *only* for the New Product Scenario or *only* for the Substantial Likelihood Scenario. It may of course decide to create the rebuttable presumption for both these scenarios, but that would be going beyond what is mandated by Art 34(1).

13 The next two sections provide some background information on the New Product Scenario and the Substantial Likelihood Scenario.

A. New Product Scenario

14 The New Product Scenario was favoured by the EC during the negotiations for the TRIPS Agreement. In its proposal, the rebuttable

16 Note that the first sentence of Art 34(1) calls for a general obligation to ensure that "the judicial authorities shall have the authority to order the defendant to prove that the process to obtain [the defendant's] identical product is different from the patented process", but it is the second sentence that creates the specific obligation to create the rebuttable presumption in certain circumstances.

17 Note that there is a type of patent claim which is sometimes referred to as a "product-byprocess" claim. A product-by-process claim seeks protection for a *product*, one that is defined or characterised by the process by which it is produced. Therefore, a patent granted in respect of a product-by-process claim is, in essence, a *product* patent: see para 4.12 of the *Guidelines for Examination in the European Patent Office* (European Patent Office, March 2024) and para 2.72 of the *Examination Guidelines for Patent Applications at IPOS* (Intellectual Property Office of Singapore, 26 May 2022). As such, a product-by-process patent claim is not the concern of Art 34 (which is targeted at process patents).

18 This is clear from the wording of Art 34(1) alone: "Members shall provide, in at least one of the following circumstances …". But for some reason, it was thought necessary to enact Art 34(2) to lay to rest any doubt on this point.

presumption was mandated if: (a) the subject matter of a patent was a process for obtaining a new product; and (b) the same product was produced by the defendant.[19] The first condition is effectively the New Product Scenario. The Substantial Likelihood Scenario did not feature at all in the EC's proposal.

15 The EC submitted this proposal for consideration in March 1990. At that time, this proposal reflected the state of affairs in the patent law of some of the EC member states such as Germany,[20] Spain[21] and the UK.[22] Amongst this group, Germany was the first to enact a rebuttable presumption for the New Product Scenario. The historical context for the German model is important for understanding why the rebuttable presumption was limited to the New Product Scenario.

16 Germany had had a rebuttable presumption applicable in infringement actions for process patents since 1891. This took the form of s 47(3) of the German Patent Act of 7 April 1891 ("German Patent Act 1891"). This provision was enacted in the era when Germany, in a bid to make medicine more accessible and affordable for its people, imposed a ban on the patenting of a new pharmaceutical substance;[23] *ie*, its inventor could not get a product patent for this new substance *per se*. The ban, however, did not extend to the patenting of the process or method of manufacturing a pharmaceutical substance. The idea was to grant the inventor of a new pharmaceutical substance some measure of protection for his contribution via a *process* patent instead: he could stop his competitors from using the patented process to obtain this new substance, but not if a different process was used. Since there would usually be a time lag between the launch of the new pharmaceutical substance in the market and the discovery of other ways of making it, the inventor's process patent would give him at least a first mover advantage. However, there was a problem with this scheme of rewarding the inventor via a process patent, namely, it might merely exist as a theoretical possibility because, as discussed earlier, the patentee would face considerable difficulties proving that the process used to obtain the rival's product was

19 Draft Agreement on Trade-Related Aspects of Intellectual Property Rights, (29 March 1990), MTN/GNG/NG11/W/68, Art 24(4).

20 Patent Act of 16 December 1980 (Germany) s 139(3).

21 Patent Act (Law 11/1986) (Spain) Arts 61(2)–61(3).

22 Patents Act 1977 (c 37) (UK) s 100.

23 Vilhelm Schröder, "Reversed Burden of Proof and the Protection of Trade Secrets in European Pharmaceutical Patent Litigation: Part 1" (2017) 39 *European Intellectual Property Review* 211 at 215.

indeed the patented process.[24] The enactment of s 47(3) of the Patent Act 1891 was to mitigate this problem.

17 Germany lifted the ban on the patenting of new substances in the 1960s,[25] but it did not repeal s 47(3). In fact, when Germany enacted a new patent law in 1980, it chose to retain the essence of this rebuttable presumption. The provision is s 139(3) of the German Patent Act of 16 December 1980, which is set out below:

> If the subject matter of a patent is a process for obtaining a new product, the same product when produced by any other party shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting his manufacturing and business secrets shall be taken into account.

The wording of s 139(3) is the one that the EC put forward in its proposal for discussion during the negotiations of the TRIPS Agreement.

18 When the EC's proposal is understood in light of the historical context for the German model – it was to compensate inventors of pharmaceutical substances who were denied a patent for their product even though this product was new by the standards of patent law – it points to the linkage between the New Product Scenario and the novelty criterion in patent law. That is, "a *new* product" in the New Product Scenario refers to a product that satisfies the *novelty* criterion for the grant of a patent.

B. Substantial Likelihood Scenario

19 Whilst the EC was in favour of the New Product Scenario, the US preferred the Substantial Likelihood Scenario. The US has had a rebuttable presumption for the Substantial Likelihood Scenario in its patent law since 1988. The pertinent provision is §295 of the US Patent Act.[26] The legislative history of this provision is instructive as to why the Substantial Likelihood Scenario was preferred over the New Product Scenario.

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24 According to Prof Joseph Straus, a well-known German professor of intellectual property law, it was "almost impossible" for the inventor-patentee to detect which manufacturing process was used to obtain the rival's product: Joseph Straus, "Reversal of the Burden of Proof, the Principle of 'Fair and Equitable Procedures' and Preliminary Injunctions under the TRIPS Agreement" (2000) 3 *World Intellectual Property Journal* 807 at 810.

25 Miguel Vidal-Quadras Trias de Bes, "Process Patents on New Products and Reversal of Proof: Factors Contributing to the Interpretation of its Scope" (2002) 24 *European Intellectual Property Review* 237 at 237.

26 35 USC (US).

20 §295 of the US Patent Act was enacted via the Process Patent Amendments Act 1988.[27] The committee which was tasked to study the bill to this Amendment Act noted the difficulties faced by the patentee of a process patent when proving that the defendant had used this process. It also noted that the solution to this problem adopted by many of the US's trading partners was to enact a rebuttable presumption for the New Product Scenario. However, this solution did not appeal to the committee for the following reasons:[28]

> The drawbacks of this approach may be illustrated by the recombinant DNA processes for producing naturally occurring substances, which cannot themselves be patented and which are in no sense 'new'. Thus, this approach would deprive some of the most important process innovators of the value of the presumption. The Committee rejects this approach because there is no clear justification for discriminating against certain types of process inventions. In order to secure a patent, a new process must be deemed useful, novel and unobvious—the same criteria that are applied to product inventions. If a process invention satisfies these criteria, then it is in the interests of society to have it publicly disclosed in return for a limited period of exclusivity for the inventor, regardless of whether the process leads to a 'new' or 'old' product.

21 Interestingly, the committee's explication of the New Product Scenario linked the reference to "a *new* product" in this scenario to the *novelty* criterion in patent law. This, as we have seen, is consistent with the intent of the New Product Scenario as conceived in the German Patent Act 1891.

22 In place of the New Product Scenario, the committee outlined the following scenario which in its view justified the application of a rebuttable presumption:[29]

> *First, the patentee must demonstrate on the basis of the evidence that is available that a 'substantial likelihood' exists that the product was made by the patented process*. Such evidence could include chemical analysis of the product or indications or 'marks' on the product itself, as well as expert testimony regarding known methods of production at costs that would justify sale of the product at the prices being charged. Exactly how much evidence will be needed in particular situations to satisfy the 'substantial likelihood' condition will depend on the circumstances, However, the patentee's burden would be less than that of proving successfully at trial by a fair preponderance of the evidence that a product in question was in fact made by the patented process but would be more than a slight possibility that the product was so made. *Second, the patentee must show that he or she has made a reasonable effort to determine what process*

27 The Process Patent Amendments Act 1988 is found in Pt IX Subtitle A of the Omnibus Trade and Competitiveness Act 19 USC (US) (1988).

28 *Senate Report No 100-83* (100th Congress, 1st session, 23 June 1987) at p 45.

29 *Senate Report No 100-83* (100th Congress, 1st session, 23 June 1987) at pp 57–58.

> *was used in the manufacture of the product in question and was unable to do so.* The reasonableness of the effort would include the use of discovery procedures under the Federal Rules of Civil Procedure or other good-faith methods, such as requesting the information from the manufacturer, if not subject to U.S. jurisdiction. These limitations on the availability of the presumption should make it available to patent owners who might otherwise be left with no remedy against an infringer, and should also adequately safeguard the rights of competitors. [emphasis added]

23 Herein lies the birthplace of the Substantial Likelihood Scenario. This was eventually enacted as §295 in the US Patent Act in the following terms:

> In actions alleging infringement of a process patent based on the importation, sale, offer for sale, or use of a product which is made from a process patented in the United States, if the court finds—
>
> (1) that a substantial likelihood exists that the product was made by the patented process, and
>
> (2) that the plaintiff has made a reasonable effort to determine the process actually used in the production of the product and was unable to so determine,
>
> the product shall be presumed to have been so made, and the burden of establishing that the product was not made by the process shall be on the party asserting that it was not so made.

24 Although the US rejected the New Product Scenario for itself, it did not see the need to prevent other countries from adopting this approach in their domestic patent law. It was, in fact, the US which proposed that WTO members have the option to provide for the rebuttable presumption in the New Product Scenario *or* the Substantial Likelihood Scenario.[30] This proposal was accepted and adopted in Art 34(1).

C. Implementation of Art 34 by WTO members

25 To recap, the rebuttable presumption in Art 34(1) is mandated only in certain circumstances: if the patent is for a process for obtaining a product, and if the defendant's product is identical with the product obtained by the patented process, the rebuttable presumption must be provided at least for the New Product Scenario *or* for the Substantial Likelihood Scenario. This is the minimum expected of a WTO member.

30 Draft Agreement on Trade-Related Aspects of Intellectual Property Rights Communication from the United States, (11 May 1990), (MTN/GNG/NG11/W/70), Art 24(3).

It may of course decide to go beyond this minimum requirement and provide the rebuttable presumption for both these scenarios – and more.

26 The following is a sampling of the different routes taken by WTO members to give effect to Art 34(1):

(a) Countries which provide the rebuttable presumption only for the New Product Scenario: Germany (the originator of this scenario),[31] China,[32] Japan,[33] Taiwan[34] and the UK.[35]

(b) Countries which provide the rebuttable presumption only for the Substantial Likelihood Scenario: the US (the originator of this scenario)[36] and Australia.[37]

(c) Countries which provide the rebuttable presumption for both the New Product Scenario and the Substantial Likelihood Scenario: France[38] and India.[39]

(d) A country which provides the rebuttable presumption for both scenarios and more: Malaysia.[40]

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31 Patent Act of 16 December 1980 (Germany) s 139(3). Other EU member states in this group include Spain, Italy, Ireland and Luxembourg.

32 Patent Law of the People's Republic of China 2006 (China) Art 61. For an analysis of the position in China, see He Huaiwen, "'Extended Protection' and Reversal of Burden of Proof in Respect of Patented Process for Obtaining New Product: Comments on Supreme People's Court's Review of *Zhang Xitian* Case (No *Mintizi* 84/2009)" (2011) 2 *China Patents & Trademarks* 11.

33 Patent Act (Act No 121 of 1959) (Japan) Art 104.

34 Patent Act (Taiwan) Art 99.

35 Patents Act 1977 (c 37) (UK) s 100.

36 Patent Act 35 USC (US) §295.

37 Patents Act 1990 (Cth) s 121A. For a case that considered this provision, see *Calix Limited v Grenof Pty Ltd* [2023] FCA 378. Note the court's explanation for this provision at [86], namely, it is primarily targeted at cases where the plaintiff-patentee had access to the defendant's product, but not the defendant's process because, *eg*, the process was used by a third party overseas and thus unavailable for inspection by the plaintiff.

38 Intellectual Property Code (France) Art L615-5-1. For a comment on the French position, see Joseph Straus, "Reversal of the Burden of Proof, the Principle of 'Fair and Equitable Procedures' and Preliminary Injunctions under the TRIPS Agreement" (2000) 3 *World Intellectual Property Journal* 807 at p 187.

39 Patents Act 1970 (Act 39 of 1970) (India) s 104A.

40 Patents Act 1983 (Act 291) (M'sia) s 36(4). It provides as follows: "For the purposes of this [infringement] section, if the patent has been granted in respect of a process for obtaining a product, the same product produced by a person other than the owner of the patent or his licensee shall, unless the contrary is proved, be taken in any proceedings to have been obtained by that process." In other words, there is only one condition to satisfy to activate the rebuttable presumption, namely, the defendant's product is the same as the patentee's (or his licensee's) product. In this author's view, this approach is overly generous towards the patentee of a process patent: it is almost

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27 Notably, Germany and France are not in the same group – at least for now. Moving forward, there is likely to be a convergence on this issue within the EU now that the Unified Patent Court is a reality.[41] This is because the Agreement on a Unified Patent Court[42] (the "UPCA") has a provision creating the rebuttable presumption which the Unified Patent Court would apply in infringement proceedings involving process patents. This is Art 55 of the UPCA:

> **Reversal of burden of proof**
>
> 1. Without prejudice to Article 24(2) and (3), if the subject matter of s patent is a process for obtaining a new product, the identical product when produced without the consent of the patent proprietor shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process.
>
> 2. The principle set out in paragraph 1 shall also apply where there is a substantial likelihood exists that the identical product was made by the patented process and the patent proprietor has been unable, despite reasonable efforts, to determine the process actually used for such identical product.
>
> 3. In the adduction of proof to the contrary, the legitimate interests of the defendant in protecting its manufacturing and trade secrets shall be taken into account.

28 Article 55(1) applies the rebuttable presumption to the New Product Scenario whilst Art 55(2) extends it to the Substantial Likelihood Scenario. This dual-scenario approach does seem to be gaining traction.

29 In the case of Singapore, there is a view that the dual-scenario approach is also adopted. This author thinks otherwise. Although the two scenarios are mentioned in the Singapore provision that implements Art 34 of the TRIPS Agreement, the unfortunate effect of the Singapore provision is to limit the rebuttable presumption to the New Product Scenario. The next section elaborates on this curious implementation of Art 34.

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tantamount to granting this patentee a *product* patent (*ie*, a patent over the product produced by the patented process).

41 The Unified Patent Court started on 1 June 2023. It was established to provide a centralised framework for patent litigation in Europe.

42 At the time of writing, 17 EU member states (including Germany and France) have ratified the Agreement on a Unified Patent Court.

III. The curious case of Singapore's implementation of Art 34

30 Section 68 of the Singapore Patents Act 1994 is the provision that gives effect to Art 34 of the TRIPS Agreement. The full text of s 68 is set out below:

> **Reversal of burden of proof**
>
> **68.**—(1) In any proceedings for the infringement of a patent, where the subject matter of the patent is a process for obtaining a new product, the burden of proving that a product is not made by the process is on the alleged infringer if the product is new or a substantial likelihood exists that the product is made by the process and the proprietor of the patent has been unable through reasonable efforts to determine the process actually used.
>
> (2) In considering whether a party has discharged the burden imposed upon him by this section, the court shall not require him to disclose any manufacturing or commercial secrets if it appears to the court that it would be unreasonable to do so.

31 Both the New Product Scenario and the Substantial Likelihood Scenario are mentioned in s 68(1). This certainly suggests that the draftsman intended to make the rebuttable presumption available in a case which satisfies the New Product Scenario or the Substantial Likelihood Scenario. From this point of view, the rebuttable presumption is available to both scenarios.

32 However – and perhaps inadvertently – the draftsman also framed s 68(1) with an overarching condition that must be satisfied, regardless of whether the plaintiff's case is based on the New Product Scenario or the Substantial Likelihood Scenario. This overarching condition is found in the opening words of the provision: "In any proceedings for infringement of a patent, where the subject matter of the patent is a process for obtaining a *new* product" [emphasis added]. The presence of the word "new" in this overarching condition, in effect, means that this overarching condition is the same as the New Product Scenario. Thus, if this overarching condition is satisfied, so is the New Product Scenario. On the other hand, if this overarching condition is not satisfied, s 68(1) has no application whatsoever, even if the plaintiff can fit the facts of his case into the Substantial Likelihood Scenario. To put it in another way, the presence of the word "new" in the overarching condition renders the Substantial Likelihood Scenario mentioned in s 68(1) otiose. Consequently, the rebuttable presumption in s 68(1) is really applicable *only* to the New Product Scenario. By way of contrast, the equivalent overarching condition in Art 34(1) of the TRIPS Agreement only requires that the subject matter of the patent is "a process for obtaining a product"; there is no requirement that the resulting product is a new product.

33 There are two Singapore cases where s 68(1) was considered, namely, *Merck & Co Inc v Pharmaceutical Singapore Pte Ltd*[43] ("*Merck*") and *Millennium Pharmaceuticals, Inc v Zyfas Medical Co*[44] ("*Millennium Pharmaceuticals*"). In these two cases, the High Court held that s 68(1) would be successfully invoked if the plaintiff proved that the facts of the case fell within the New Product Scenario or the Substantial Likelihood Scenario.[45] In both cases, the courts found that the product made by the patented process was not a new product (and hence the New Product Scenario was not an option), and went on to consider if the plaintiff could make out a case based on the Substantial Likelihood Scenario. With all respect to the courts, the author submits that it is not possible to ignore the presence and delimiting impact of the overarching condition in s 68(1). A summary of the approach taken in these two cases is provided below.

34 In *Merck*, there were two claims in the infringement action. The first claim related to the plaintiff's product patent for a chemical compound which the plaintiff called "Lovastatin" which had a dimer impurity of 0.2% or less. This infringement claim was dismissed because the defendant successfully challenged the validity of this product patent. The High Court agreed with the defendant that Lovastatin did not satisfy the novelty criterion, *ie*, it was not a new product for the purposes of a grant of patent,[46] and accordingly it ordered the revocation of the product patent for Lovastatin. The second infringement claim related to the plaintiff's process patent for making Lovastatin. This was where s 68(1) came into the picture. The plaintiff sought the application of the rebuttable presumption in s 68(1) to shift the burden to the defendant to prove that its product, which had a dimer impurity of 0.2% or less, was not made by the patented process. The High Court held that, given its finding in the validity challenge that Lovastatin did not satisfy the novelty criterion, it could not be said to be a "new product" for the purposes of the New Product Scenario in s 68(1). The only other option, the court noted, was for the plaintiff to fit its case into the Substantial Likelihood Scenario. This, the plaintiff failed to do and accordingly the court refused to apply the rebuttable presumption in this case.

43 [1999] 3 SLR(R) 1072.

44 [2023] SGHC 360.

45 See *Merck & Co Inc v Pharmaceutical Singapore Pte Ltd* [1999] 3 SLR(R) 1072 at [54] and *Millennium Pharmaceuticals, Inc v Zyfas Medical Co* [2023] SGHC 360 at [96].

46 The High Court also found that Lovastatin did not satisfy the inventive step criterion. Note that, on appeal, the Court of Appeal came to a different conclusion: it found that Lovastatin was new but it lacked an inventive step: *Merck & Co Inc v Pharmaceutical Singapore Pte Ltd* [2000] 2 SLR(R) 708. Thus, the order to revoke product patent for Lovastatin was upheld.

35 In *Millennium Pharmaceuticals*, the infringement action related to a claim[47] in the process patent for a method of making a type of boronic acid and its use in the preparation of a known compound called "bortezomib".[48] The defendant's product contained bortezomib as an active ingredient. The plaintiff activated s 68(1) to get the benefit of the rebuttable presumption, and to leave the defendant to prove that its product was not made by the claimed process. The plaintiff's case under s 68(1) was based on the Substantial Likelihood Scenario. The High Court explained that this was because the New Product Scenario was not an option open to the plaintiff since bortezomib was a known compound.[49] But the court found that the plaintiff was unable to make out its case on the Substantial Likelihood Scenario and hence it refused to apply the rebuttable presumption in the case.

36 One other point in the two decisions merits a mention. In both cases, there was a link made between the New Product Scenario in s 68(1) and the novelty criterion for a grant of patent. This link was a very direct and explicit one in *Merck*: the High Court held that, given that Lovastatin was not a new invention for the purposes of the novelty criterion, it could not be said to be a "new product" for the purposes of s 68(1). In coming to this conclusion, the High Court defined a "new product" in s 68(1) to include "anything not known in the state of the art, including an improvement".[50] Significantly, the reference to "state of the art" in this definition is a term used in the novelty inquiry.[51] In *Millennium Pharmaceutical*, the High Court also made the link when it determined that bortezomib was not a "new product" for the purposes of s 68(1) because it was "known in the state of the art".[52]

37 The link that was made between a "new product" in s 68(1) and the novelty requirement is, as we have seen, consistent with the original intent of the New Product Scenario as conceived in the German Patent Act 1891. This interpretation is also supported by the fact that the draftsman chose to use the same word "new" in both ss 68(1) and

47 This claim is Claim 1(b)(ii) in Patent SG322. Note that the plaintiffs also alleged infringement of other claims in their process patents, but these claims were found to be invalid for lack of novelty and an inventive step.

48 The fact that bortezomib is a known compound is recorded in the judgment: see *Millennium Pharmaceuticals, Inc v Zyfas Medical Co* [2023] SGHC 360 at [5].

49 *Millennium Pharmaceuticals, Inc v Zyfas Medical Co* [2023] SGHC 360 at [97].

50 *Merck & Co Inc v Pharmaceutical Singapore Pte Ltd* [1999] 3 SLR(R) 1072 at [57].

51 In Singapore, see s 14(1) of the Patents Act 1994 (2020 Rev Ed): "An invention shall be taken to be new if it does not form part of the state of the art."

52 *Millennium Pharmaceuticals, Inc v Zyfas Medical Co* [2023] SGHC 360 at [97].

14(1), which is the provision in the Patents Act 1994 that defines the novelty criterion.[53]

IV. Need for reform in Singapore

38 The author has alluded to her suspicion that the legislative intent was to make the rebuttable presumption in s 68(1) available in both the New Product Scenario and the Substantial Likelihood Scenario. In the author's view, the draftsman's implementation of this intent fell short of this mark. By framing or subjecting the application of s 68(1) to an overarching condition requiring "the subject matter of the patent [to be] a process for obtaining a *new* product" [emphasis added], the only option for the patentee is to fit his case into the New Product Scenario. Whilst the decisions in *Merck* and *Millennium Pharmaceuticals* extended s 68(1) to encompass the Substantial Likelihood Scenario, they are difficult to justify from the point of view of statutory interpretation. This state of affairs is hardly ideal. Legislative amendments are thus in order.

39 The amendment that is most needed is an obvious one: delete the word "new" in the overarching condition in s 68(1). This amendment would give effect to the legislative preference for the broader approach and endorse the decisions of the High Court in *Merck* and *Millennium Pharmaceuticals*. Importantly, there are policy reasons for preferring the broader approach. As explained in the context of Art 34 of the TRIPS Agreement, the creation of the rebuttable presumption for patents for a process for obtaining a product is to address the concern that the patentees might otherwise only have a "paper" protection because of the difficulties in enforcing their process patent. The degree of difficulty may differ, but this is a challenge faced by all patentees of process patents, those whose process obtains a new product and those whose process obtains a known product. Providing the rebuttable presumption only to the first group of patentees is to unfairly discriminate against the second group of patentees. As the US committee had observed when it rejected such a limitation, inventions relating to a process for obtaining an "old" product contribute to society as much as inventions relating to a process for obtaining a "new" product.[54] The discrimination is made worse by the

53 In *Magnesium Elektron Ltd v Molycorp Chemicals & Oxides (Europe) Ltd* [2016] RPC 18 at [30], the English High Court reasoned that, given the same word "new" was used in the UK provision on the rebuttable presumption as well as in the UK provision on the novelty criterion, this word must mean the same thing in these two provisions.

54 Miguel Vidal-Quadras Trias de Bes, "Process Patents on New Products and Reversal of Proof: Factors Contributing to the Interpretation of its Scope" (2002) 24 *European Intellectual Property Review* 237 at 237.

fact that a "new" product for the purposes of the New Product Scenario is currently assessed by reference to the novelty criterion. The threshold set by this criterion is a high one, so high that it has been said to be a "formidable requirement".[55] Consequently, it is very difficult indeed to activate s 68(1) successfully via the New Product Scenario route.[56] Ironically, the patentee who can cross the high threshold set by the New Product Scenario may not need the rebuttable presumption. This is because he may be able to get a patent for the resulting "new" product *per se*,[57] in which case he would just rely on his product patent and thereby avoid the problems of enforcement associated with a process patent.

40 There are two other amendments to s 68(1) that the author would recommend. The first relates to another condition mentioned in Art 34(1) but is currently absent in s 68(1), namely, the defendant's product must be identical with the product obtained by the patented process. Singapore is certainly at liberty to omit this condition in its implementation of Art 34; as mentioned earlier, Art 34 only sets out the minimum that is expected of WTO members. However, in the author's view, this condition should be included in s 68(1) because, if the defendant's product is not the same as the product obtained by the patented process, what is the basis for the patentee's suspicion that the patented process was used to make the defendant's product?

41 The last proposed amendment is the least important and might even be regarded as a pedantic point. At the moment, s 68(1) does not explicitly provide that the defendant's product is presumed to be obtained by the patented process; this presumption is an implicit one. By way of contrast, the language of Art 34(1), especially its use of the word "deems", is explicitly geared towards the creation of a presumption (which is for the defendant to rebut).[58] For greater clarity on what s 68(1) is intended

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55 *Rohm and Haas Electronic Materials CMP Holdings, Inc v NexPlanar Corp* [2018] 5 SLR 180 at [49]. See also *Institut Pasteur v Genelabs Diagnostics Pte Ltd* [2000] SGHC 53 at [188], where the High Court opined that the novelty criterion is "strict" to the patentee.

56 For this reason, it has been said that s 100(1) of the UK Patents Act 1977, which only provides the rebuttable presumption for the New Product Scenario, has "quite narrow application": *Crystal Fibres v Fianium* [2009] EWHC 2149 (Pat) at [24].

57 This would be the case where the resulting "new" product satisfies the other patentability criteria, in particular, it must involve an inventive step and is capable of industrial application as required by s 13(1) of the Singapore Patents Act 1994 (2020 Rev Ed).

58 This is also the case in many of the provisions in the national patent laws of WTO members implementing Art 34: see, *eg*, s 100(1) of the UK Patents Act 1977 (which provides that, unless the contrary is proved, the defendant's product "shall be taken" to have been produced by the patented process); and §295 of the US Patent Act 35 USC (which provides that the defendant's product "shall be presumed" to have been

(cont'd on the next page)

to do, the implicit rebuttable presumption in this provision should be made explicit.

V. Conclusion

42 Section 68 of the Singapore Patents Act 1994 is important in infringement proceedings involving process patents. If the patentee can satisfy the conditions laid down in s 68, the patentee gets the benefit of a presumption that an essential element in the infringement claim is fulfilled and it is for the defendant to prove otherwise. This article seeks to throw some light on the whys and wherefores of this rebuttable presumption. In particular, it traces the origins of s 68 to Art 34 of the TRIPS Agreement, unpacks the nature of the rebuttable presumption mandated by Art 34, and compares and contrasts the Singapore version with the international version.

43 In the author's opinion, the current wording of s 68 limits its application in a way that was probably unintended by the Legislature in Singapore. There are two High Court decisions which have taken a broader approach to s 68, but this interpretation of s 68 is difficult to justify because it is tantamount to ignoring an explicit overarching condition in the provision that has a drastic delimiting effect. The author herself prefers the broader approach because there are good policy reasons for adopting the broader approach. Hence, the author respectfully submits that it is time for the Legislature to have a relook at s 68.

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made by the patented product and the burden of establishing that the product was not made by the process shall be on the defendant).