for assistance made by the needy country.[1041] Rather than providing for an 'effective' system, the lack of guidance will more likely add to the uncertainty and absence of clarity. The existence of a large generic pharmaceutical sector in India and their supply of low cost generics have proven to be of great assistance to countries, in particular LDCs. Perhaps this track record will spur countries without an adequate pharmaceutical sector to seek assistance in India.

C. EC

Patent law is a national prerogative within the EC. Notwithstanding this, the EC is required to ensure that national legal systems do not bring about the distortion of competition between the common market Members and reserves the right to make appropriate rules with the unanimous consent of the EC Council.[1042] Upon this basis and the representative role the EC plays for its Member countries in the WTO the EC Commission decided to draft a regulation that would regulate and harmonise the implementation of the Article 31*bis* system into the domestic legal systems of all EC Members.[1043]

On the 17th of May 2006 the EC Regulation No. 816/2006 on 'compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems' was adopted (the 'EC Regulation').[1044] Being a regulation applies directly and overrides EC Member law.

The EC Regulation represents an uneasy balance between the facilitation of the Article 31*bis* exceptions and the protection of patent rights. The unease with the exception to Article 31(f) is evident in the introduction and solidification of comprehensive safeguard measures. In doing so the EC Regulation keeps close affinity to the terminology used in Article 31*bis*. Despite the adoption of definitions and concepts, the EC Regulation does not make reference to the Chairman's Statement.[1045] Notwithstanding this, the EC centres the regulation around the good faith use of the system.

1041 Compare India in the TRIPS Council Minutes (15.09.2005) IP/C/M/48 p. 26.

1042 The EC justified its intervention on Arts 95 (providing for the approximation of laws) and 133 (creation of a common commercial policy). Cf. EC Commission Proposal for a Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems COM(2004)737 (29.10.2004) ('EC Proposal') 5-6, *Hilf*, 6 EJIL 2 (1995) p. 245.

1043 The use of the regulation as a tool to implement the system was chosen to expedite the implementation of the system. Had the EC Members have been required to transpose a directive, the system would have required far longer to become operational. Cf. *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

1044 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation').

1045 *Cornides*, 10 JWILP 1 (2007) p. 71.

The EC Regulation responded to criticisms[1046] of its proposal presented in 2004[1047] and adopted a system that more aptly reflects the spirit and intention of Article 31bis and the Public Health Declaration. To this extent the eligible beneficiary countries were not limited to WTO Member States.[1048] EC Member States may implement additional requirements for the granting of a license however these additional requirements may not place unnecessary costs or burdens of the license applicant.[1049] Unlike the Canadian approach, the EC Regulation permits the prior negotiation requirement to be waived in instances of extreme urgency and public non-commercial use.[1050] In other instances the negotiation period is limited to 30 days. The distinction between licenses granted for extreme urgency or public non-commercial use ground and other licenses is also relevant to the calculation of the remuneration. In the former instances the remuneration is limited to 4% of the total price paid.[1051] The EC Regulation also adopts a system that is better able to react to every-day changes. Hence, the extension of a license on the grounds that the amount permitted under the license is no longer sufficient is permitted under the EC rules.[1052] Absent from the EC Regulation is an obligation to question or review the necessity or authenticity of the importing country's request.[1053] Further practical provisions include the 'compulsory licensing' of supplementary protection certifi-

1046 *t'Hoen*, (2005).

1047 EC Commission Proposal for a Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems COM(2004)737 (29.10.2004) ('EC Proposal').

1048 In terms of Art 4(a and c) of the EC Regulation any LCD and low income country (with a gross national product per capita of US$ 745 and included in the OECD Development Assistance Committee's list) may partake in the EC system. Art 5 thereof sets out the procedures required in order for such countries to participate. Excluded from the EC Regulation is the obligation that the prior negotiations be conducted on 'reasonable commercial terms'. Compare *Cornides*, 10 JWILP 1 (2007) p. 72.

1049 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 6(4).

1050 The EC Proposal did not contain a waiver. Instead it merely permitted a shorter negotiation period for extreme urgencies.

1051 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 10(9). The conditions for determining the amount of remuneration appears to permit license fees in excess of 4% for licenses not granted within the scope of government use or extreme urgencies. Recital 15 states further that the 4% should be used as a 'reference point' when deliberating adequate remuneration, i.e. also during the prior negotiation. Compare *Cornides*, 10 JWILP 1 (2007) p. 72.

1052 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 16(4). The simplified extension procedure only relates to the amount and only to a maximum of 25% more than was initially requested.

1053 This may however occur in an indirect manner. Art 10(2) limits the amount necessary to the importing country's needs – not its request. Accordingly, it is possible that a granting authority could question whether the needs are indeed being fulfilled.

cates. This ensures that licenses are not hindered by the supplementary rights afforded to certain pharmaceutical patent holders. A further practical measure is that the licensee 'may avail' himself to the European safety and efficacy procedures.[1054] The option to use this system may be of significant assistance where the importing state has insufficient means to do so itself. In this vein, the EC Regulation also permits license holder to circumvent certain EC regulations concerning the production and sale of pharmaceuticals within the EC (e.g. proof of pre-clinical trials).[1055] To the extent that the producer can demonstrate that his product is a generic of a pharmaceutical already subjected to clinical trials and tests and authorised for marketing, the producer will be able to avail himself to the data presented by the original producer. Accordingly, the EC Regulation implicitly extends the compulsory license to undisclosed information protected under Article 39 of the TRIPS Agreement.[1056]

The EC Regulation is however a more restrictive system than that permitted by Article 31*bis*.[1057] In terms of the application requirements for a license, the applicant must provide a specific request from the government of the needy country or its representatives (this including NGOs and international UN or health bodies). Accordingly, private requests from the needy country will not be able to benefit under the EC system. The EC system is also limited to pharmaceuticals for human treatment.[1058] This restriction is not required by Article 31*bis*. Further, a license may not be granted for an unlimited period.

The Commission was unwilling to create a process whereby it would eliminate the patent holder from the license process. In this regard, the requirement of prior negotiations was expressly dealt with and, where deemed unnecessary, the EC Regulation obliges the licensing authority to notify the patent holder of a license application for the relevant patent and grant the patent holder the opportunity to make a comment. Additional safeguards for the patent holders' rights are evident in the form of a comprehensive oversight system by the relevant customs authorities. The EC Regulation establishes a detailed procedure for dealing with diverted licensed products. Not only are the customs authorities required to suspend or detain products, they are also obliged to provide verify the source, its purpose and provide opportuni-

1054 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 18.

1055 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 18(2).

1056 Cf. *Cornides*, 10 JWILP 1 (2007) p. 72.

1057 The EC Regulation bases this strict approach on a desire to 'create a secure legal framework and discourage litigation'. Cf. EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation' recital 6.

1058 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 2(1).

ties for the interested parties to provide information in regard to the shipment.[1059] The EC Regulation also permits the granting authority to oblige the license holder to maintain records and books that will verify the shipment process and prove that the products have arrived in the importing country.[1060] These recordkeeping requirements would be aimed at ensuring the license conditions are fulfilled.

Although these and other provisions regulate issues not expressly dealt with in Article 31*bis* they merely provide additional structure to the somewhat abstract system set out in Article 31*bis*.

The EC Regulation states that the termination of the license may be ordered where the license conditions have not been met. In the EC Proposal the termination was qualified and only required when the circumstances that led to the license grant are 'unlikely to recur'. The removal of this element of discretion indicates a departure from the Article 31(g) of the TRIPS Agreement and less protection for the license holder. This omission is an erosion of the license holder's safeguards and confirmation that the EC has adopted a strict system of ensuring that the licensed products are not diverted. Further safeguards are implemented by the granting authority. In this regard the authority must ensure that the amount stated in the importing country's request is not duplicated in other EC Member States. This control mechanism is coordinated in conjunction with the EC Commission.

The EC Regulation lays particular emphasis on ensuring that the license is used for the purposes intended in Article 31*bis*. This is no more evident in the sentence '[t]he license shall be strictly limited to all acts necessary'.[1061] This safeguard is directed not only at the product but also at the quantity, manufacture, distribution and destination. Although these requirements flow from Article 31*bis*, they give the impression that no latitude will be tolerated. To this extent the Dutch system may be required to apply its Article 31*bis* system in a more restrictive manner.

As the EC Regulation serves to establish 'a procedure for the grant of compulsory licenses' in relation to Article 31*bis*, all EC Member States will be obliged to grant such licenses in accordance with the EC Regulation. The effect is therefore that the market for producers of pharmaceutical products in accordance with Article 31*bis* has extended to the entire EC.

1059 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 14.

1060 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 10(8).

1061 EC Regulation on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems EC 816/2006 L 157/1 ('EC Regulation') Art 10(4).

F. Related measures taken to reflect the Public Health Declaration

The reaction to the Public Health Declaration and the subsequent TRIPS decisions has been multifarious. National governments have taken steps to alter their domestic policies and legislation, countries interacting with one another have reflected the policies of the Public Health Declaration either expressly or tacitly and international bodies have recognised the contents in one way or the other. A brief sampling of the measures taken is dealt with below.

I. International and multilateral policies and measures

International bodies such as the WHO Assembly and the UN Commission on Human Rights have been vocal on propagating the use of the TRIPS flexibilities.[1062] In the May of 2004 the WHO Assembly, whilst taking into account the Public Health Declaration and the Decision, urged countries as 'a matter of high priority':

> 'to consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights;
>
> …
>
> to encourage that bilateral trade agreements take into account the flexibilities contained in the WTO TRIPS Agreement and recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health'.[1063]

International bodies have also taken the view that the Public Health Declaration has clarified the use of compulsory licenses and that Member States can take compulsory license measures without fear of threats or reprisals from industry or foreign governments.[1064]

II. Bilateral policies and measures

The move towards more comprehensive bilateral trade relationships has resulted in the negotiating parties often including obligations on intellectual property rights. This has especially been evident in bilateral free trade agreements involving the

1062 WHO World Health Assembly Resolution 'Global Health-sector Strategy for HIV/AIDS' (28.05.2003) WHA56.30 at 2, UNCHR Res 2004/26 'Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria' (16.04.2004) UN Doc E/CN.4/2004/L.11/Add.3 p. 58.

1063 WHO World Health Assembly 'Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS' (22.04.2004) WHA57.14 p. 3-4.

1064 *WHO/WTO*, WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat (WTO Secretariat Geneva 2002) p. 16.