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## **Public health-friendly options for protecting pharmaceutical registration data**

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**Abstract:** To gain marketing approval, generic firms typically rely on the clinical safety and efficacy testing data that brand-name pharmaceutical companies previously submitted ("registration data"). Big Pharma and the US government are pushing developing countries to provide brand-name companies with a minimum of five years exclusive rights to registration data. But restrictions on use of registration data delay the introduction of price-lowering generic competition. This paper considers public-health friendly alternatives, emphasising a cost-sharing approach, in which generic firms have an absolute right to use registration data, but must pay a proportionate share of the cost of generating the data.

**Keywords:** data exclusivity; data protection; WTO; TRIPS; compulsory licensing; misappropriation; cost-sharing; marketing approval data; registration data.

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### **1 Introduction**

As a condition of selling pharmaceuticals, countries require pharmaceutical sellers to submit data showing the drugs are safe and effective. This data is commonly referred to as registration data, or marketing approval data.

Generating the data, based on animal and human testing can be relatively expensive, costing in some cases tens of millions of dollars. It is also a time-consuming process.

Typically, when generic companies seek marketing approval, they do not repeat the safety and efficacy testing the brand-name companies originally conducted to obtain marketing approval. Instead, they show that their product is chemically identical to the brand-name, original product, and that it works the same in the body as the original product. These showings are made through 'bioequivalence testing', which is much less expensive and time consuming than the safety and efficacy testing. Drug regulators provide marketing approval based on the showing that the generic product is essentially

similar to an original product for which safety and efficacy has been established. Thus, although generic firms may not use the originators' data, they either rely on the data, or ask the government to grant marketing approval by relying on an approval of a brand-name product based on the original data.

In using or relying on an originator's data, or asking the government to use or rely on the data to give them marketing approval, do generic firms need to compensate the data generator? Should they? And, if so, how?

These questions are the subject of this paper.

In practice, these questions are answered on a country-by-country basis, according to each nation's own laws and regulations, but within the constraints imposed by international trade rules and international trade agreements.

Registration data is not an invention, and is not subject to patent protection under national law, the international rules established by the World Trade Organization (WTO)-administered agreement on Trade-related Aspects of Intellectual Property (TRIPS), or other international agreements.

However, the TRIPS agreement does require countries to protect 'undisclosed' pharmaceutical test data from 'unfair commercial use'.

Article 39.3 of the TRIPS Agreement stipulates that:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilise new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

The meaning of this provision is subject to considerable debate and controversy.

There is a very strong argument that the obscure TRIPS language simply requires countries to protect submitted test data against misappropriation.

However, brand-name drug companies, as well as some national governments, contend that the TRIPS provisions require countries to provide the originators of the data with exclusive rights to use it for an extended period, usually five years or more ('data exclusivity').

The data exclusivity approach is the norm in most industrialised countries. The US, Japan, Australia and the countries of the European Union all have data exclusivity rules in place. Most nations in Eastern Europe have data exclusivity rules, as do a number of developing countries, including especially those who have entered in bilateral or regional free trade agreements with the USA (IFPMA, 2005).

A number of bilateral and regional free trade agreements, including the USA agreements with Vietnam, Jordan, Singapore, Australia and the Central American countries, contain explicit requirements that countries provide data exclusivity.

The rationale for data exclusivity is that drug development is expensive and risky. Data exclusivity, according to its proponents, is necessary both to provide an incentive for brand-name companies to undertake R&D and to ensure that they are not placed at unfair disadvantage as against 'free-riding' generic firms (Gorlin, 2000, p.7).

Data exclusivity poses major barriers to generic entry. In general, if generic firms are not able to rely on originators' data, they will not enter the market until they are able to rely on the data. Redoing the tests conducted by brand-name companies is not only wasteful, it is frequently too time-consuming and expensive for the relatively

low-capitalised generic industry to manage. Thus data exclusivity confers an effective marketing monopoly for the term of exclusivity provided.

Where patent monopolies extend beyond the period of data exclusivity provided, data exclusivity may have little practical effect. But frequently data exclusivity will be of consequence.

The provision of exclusive rights to registration data can provide patent-like protections in cases where pharmaceuticals are not covered by patents. Such instances may occur when a pharmaceutical product does not meet the standards of patentability in a country, when the originator of the product failed or chose not to patent it in a country, when the patent term has expired, or when a compulsory licence has been issued.

This paper considers public health-friendly alternatives to data exclusivity for countries in implementing TRIPS Article 39.3, and more generally in setting policy in the area of data protection.

The paper considers four broad sets of options.

- *Bans on misappropriation.* This approach provides the lowest level of protection for registration data that is compatible with TRIPS. It bans parties from fraudulently or dishonestly gaining access to registration data and using it to seek marketing approval.
- *The cost-sharing approach to registration data.* This approach gives generic firms an automatic right to use originators' data, but requires them to pay a share of the documented costs of generating the data, proportionate to the size of the markets in which they are selling their product. It is a stylised compulsory licensing system.
- *Other approaches to compulsory licensing of registration data.* This approach included narrower options for compulsory licensing of data, including in cases where a compulsory licence has been issued on a patent.
- *Public health variants of the data exclusivity approach.* These modifications and clarifications to a strict and inflexible data exclusivity rule can advance public health objectives by limiting the scope of the data exclusivity provided, or by creating exceptions to data exclusivity.

With data exclusivity now perhaps the most controversial and heated element of international negotiations and discussions over intellectual property-related issues involving pharmaceuticals, it is paramount that countries be aware of the wide array of TRIPS-compliant policy options they have for affording data protection.

Particularly as they enter into free trade agreement negotiations and face demands for data exclusivity, it is important for countries to recognise that they have various alternatives.

This paper argues for the public health benefits of adopting a misappropriation or cost-sharing approach to registration data protection. It emphasises that the cost-sharing approach satisfies the policy rationale for providing data exclusivity, at a much lower cost, and so it strongly recommends that countries consider tabling this option when confronted with demands for data exclusivity and rejection of the misappropriation approach.

For countries that adopt data exclusivity, the paper strongly recommends public health variants designed to prevent data exclusivity-conferred marketing monopolies from undermining access to medicines and other public health objectives.

## **2 The misappropriation approach**

### *2.1 The misappropriation approach explained*

Under the misappropriation approach, countries may meet their obligations under Article 39.3 by prohibiting ‘dishonest’ uses, or misappropriation, of data submitted to gain regulatory approval.

“This would require, for example, proscribing situations in which a competitor obtains the results of testing data through fraud, breach of confidence or other ‘dishonest’ practices, and uses them to submit an application for marketing approval for its own benefit. It would also apply in cases where the government provides access to undisclosed testing data in order to provide an advantage to a firm which did not produce them or share their cost” (Correa, 2002, p.x).

With this approach, there is no grant of exclusive rights to the originator of the test data. The originator is protected against what national misappropriation law defines as unfair use of the data. However, such protections do not extend to reliance by generic firms or drug regulatory agencies on the fact of approval of the originator firm’s product.

Thus, when a generic firm seeks to enter the market for a product which is not patent protected, if it is able to produce adequate bioequivalence data, the regulatory agency will grant the generic firm marketing approval. In such a case, there is no violation of any rights held by the originator of the data, nor any compensation due the originator. Nor do they extend to uses of originator data located in the public domain. The generic firm need not compensate the original data submitter, nor seek any permission from it. Nor does the firm need to wait before it may seek marketing approval (though it still may face patent barriers to selling its product).

The misappropriation approach is grounded in an analysis of the negotiating history of Article 39.3 and of international law and country practice on ‘unfair competition’ or ‘unfair commercial practice’ (Correa, 2002, pp.25–33). It emphasises that the definition of ‘unfair’ will necessarily vary among countries, and points out that TRIPS negotiators considered but rejected proposed language requiring provision of data exclusivity.

### *2.2 Implementation of the misappropriation approach*

A number of countries currently follow this approach as their mode of implementing Article 39.3. For qualifying registration data, such countries generally prohibit disclosure of the data by government officials to third parties. But they empower government agencies to grant marketing authorisation by relying on the fact of prior approval of essentially similar products for which registration data was submitted. Countries following this approach include Argentina and Canada (Indian Institute of Foreign Trade, 2003, pp.17–23).

### *2.3 Policy rationale for the misappropriation approach*

This approach takes maximum advantage of TRIPS flexibilities. While providing for the non-disclosure of registration data, it does not impede generic firms from getting quickly to market. Generic companies are able to rely on approval by regulatory agencies of originator products, establish bioequivalence, and thereby obtain marketing approval.

This approach enables generics to reach the market as fast as possible, and with no extra registration data-related costs.

It is simple to administer, and imposes no regulatory burdens on governments.

The primary policy-based arguments against the misappropriation approach are that it will undermine brand-name company investment in R&D – or R&D in developing countries – and that it denies fair return to brand-name companies.

But there is reason to challenge whether compensation for registration data is needed to provide adequate incentive for R&D; this is especially so for developing countries. First, companies already have large incentives under the patent system to conduct R&D – 20 years marketing monopolies that in most cases will extend beyond the exclusivity period afforded by registration data protection. Second, because developing countries provide a small share of the global pharmaceutical market, their policy choices have a minimal impact on the R&D investment decisions of multinational pharmaceutical companies. Third, there is no empirical evidence that provision of enhanced patent, registration data or other such protections has increased pharmaceutical company investment in developing countries. Since the pharmaceutical market is global, the decision to invest in R&D in a country is, to a considerable degree, independent of patent, registration data or other such protections provided in that country.

The calculus may be slightly different in the case of industrialised countries. Because these countries are the markets which Big Pharma targets, there is a stronger argument that failure to provide data exclusivity, or compensation for competitors' use of registration data, may deter research for products for which companies are able to anticipate they will not be able to win patent protection but would be able to obtain exclusive or compensator rights in registration data.

A related but distinct argument from whether data protection is necessary to enable R&D is whether it is necessary to provide a fair return to the companies that conducted the clinical tests. This argument has less force for products for which companies benefit from patent protection, and is stronger in instances where patent protection cannot be obtained. There is an actual cost to conducting clinical trials, this argument runs; if generic competitors are able to rely on marketing approvals based on those trials in order to obtain their own marketing approval, they will unfairly free ride on the investment of the originator firm. To this, the misappropriation approach argues that this kind of 'free riding' occurs all the time, in a wide array of industries. Corporate investments are not normally shielded from competition, nor should they be (Correa, 2002, pp.27–29). The patent system makes special allowance for cases where inventive genius is displayed, but that specialised case should not be expanded to become the general rule.

Moreover, developing countries especially may reasonably argue that the fairness considerations to brand-name companies should be subordinated to the pressing needs of their domestic consumers, many or most of whom cannot afford monopoly-priced medicines.

Whatever the merits of the misappropriation approach, it does display a strategic problem in important contexts. In bilateral and regional free trade agreement negotiations with industrialised countries, developing countries that have suggested little more than the misappropriation approach have found their positions unsustainable. With few if any exceptions, they have simply capitulated to industrialised country demands for data exclusivity.

**Box 1** Model language for the misappropriation approach

Government authorities shall prohibit misappropriation of test or other data submitted to obtain marketing approval for pharmaceutical or agricultural chemical products which utilise new chemical entities. Except where necessary to protect the public, government authorities shall not disclose such data.

**Box 2** Model language for the cost-sharing approach<sup>2</sup>*Use of or reliance on test data submitted for pharmaceutical approval*

Parties shall be permitted to use or rely on data submitted by a prior party for the purpose of meeting government requirements for marketing approval of pharmaceuticals, or to have a government agency use or rely on the data. Such right shall be automatic, and is not subject to appeal.

*Commercial use of test data submitted for pharmaceutical approval*

When an agency requires parties, as a condition for the commercial marketing of pharmaceutical products which utilise new chemical entities, to submit test or other data, the origination of which involves a considerable effort, the agency shall require subsequent applicants that use or rely upon the originator's data, or have the government use or rely upon such data, for registration of competing products to contribute to the costs of such tests, if the following conditions are met:

- a marketing approval was obtained within the past five years
- b the person who seeks contributions to the cost of such tests and data provides the agency with public disclosures of
  - the costs of such tests or data, supported by independent verification
  - a reasonable estimate of the country's likely share of the global market
  - the amount of global revenue the product has generated to date.

*Contributions to the cost of tests*

Pursuant to Section 2, parties using or relying, or seeking to have the government use or rely, on data submitted by a previous party shall contribute to the costs of such data. The amount of the contribution shall be based upon the following.

- a The adjusted costs shall be the actual costs, except that for human use clinical trials on pharmaceutical drugs conducted before marketing approval in a major market, expenditures on phase one trials shall be multiplied by a factor of five, phase two trials shall be multiplied by a factor of two, and phase three trials shall be multiplied by a factor of 1.4.
- b Each non-originator of the data shall make a contribution equal to their pro-rata share of the adjusted costs. The pro-rata share shall be:
  - the adjusted costs
  - multiplied by the country's estimated global market share
  - multiplied by the proportion of the remaining period of protection as proportion of the five-year period
  - divided by the number of competitors.

**Box 2** Model language for the cost-sharing approach<sup>2</sup> (continued)

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| c | The contribution in (b) will be equally divided among those who have already made contributions.   |
| d | Compensation will not be required in cases where the product has generated global revenues in excess of 20 times the amount of the adjusted costs.   |
| e | To satisfy public interest considerations, the Minister of Health may, at his or her sole discretion, substitute a royalty payment not to exceed 6% in place of the amount determined pursuant to subsections a) and b) above.   |
| f | There shall be no compensation required where reliance on the data is sought for government or non-commercial purposes.  |
| g | Where the test data relates to a pharmaceutical product or process that is or was patented, adequate compensation shall be presumed awarded by virtue of the patent or licence royalties, and no additional compensation shall be provided for subsequent use or reliance on the data. |

**Box 3** Sample language for a compulsory licensing system for registration data

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| <i>Compulsory licensing of registration data</i> |   |
| a  | Where a compulsory licence has been issued on a pharmaceutical-related patent, the registration data for the pharmaceutical product incorporating that patent shall automatically be compulsory licensed as well. Third parties, including government agencies or contractors, using or relying on such information, or requesting government agencies to grant marketing approval with reference to the compulsory licensed data, shall not be required to pay compensation to data submitters for use of the data.  |
| b  | Upon application or its own initiative, and for the purpose of advancing public health objectives, the health ministry shall issue to the government or third parties non-exclusive licences to use registration data. The health ministry shall determine adequate compensation in such circumstances, not to exceed a 6% royalty.<br><br>Circumstances in which the ministry shall issue such licences include: <ul style="list-style-type: none"> <li>• instances where the price of registered medicines is a barrier to people who need them obtaining such medicines, and there is evidence that competition will lower price; and</li> <li>• instances where a third party has unsuccessfully endeavored during a reasonable period of time (e.g., 90 days) to obtain the data submitter's consent for the use of the data under reasonable terms and conditions.</li> </ul> |
| c  | Upon application or its own initiative, and to remedy anti-competitive practices or promote competition, the competition authority, shall issue to the government or third parties non-exclusive licences to use registration data. The competition authority shall determine adequate compensation in such circumstances, not to exceed a 6% royalty.  |

### 3 The cost-sharing approach

#### 3.1 *The cost-sharing approach explained*

Under the cost-sharing approach, countries meet their obligations under Article 39.3 to prevent ‘unfair commercial use’ of undisclosed registration data by providing that compensation be paid to the originators of the data when others use or rely on it.

The cost-sharing approach gives generic competitors an automatic right to rely on the registration data generated by originator companies, or marketing approval authorisations based on that data. But it does require the generic entrants to pay for use of the data (or relying on marketing approvals based on the data).

Under the cost-sharing approach, the amount generic competitors pay for using or relying on the data is based on the actual cost of generating the data and the proportionate global market share obtained by the generic competitor. Thus, the key features of such a system are:

- The originator of the data must disclose and document the actual costs incurred in generating the data.
- The generic competitor pays a share of cost apportioned to each national market. Thus, a generic competitor’s payment would be larger in a larger national market, and smaller in a smaller market. If a national market is 1% of the global market, then a generic competitor that has obtained marketing authorisation in that country will pay a portion of 1% of the cost of generating the data.

To avoid overcompensation or double compensation for originators of data, there are caps and limits on payment under the cost-sharing approach:

- if a pharmaceutical product is covered by a patent, no registration data compensation is paid
- when the company which originated the data earns from sales a certain multiple (20 times) of its cost in generating registration data, it loses its right to data compensation from generic competitors
- the right to compensation expires five years after marketing approval has been granted to data originators.

Here’s how this rule would work in the case of Indonesia, a country which represents about 0.2% of the global market. A brand-name company submits registration data and obtains marketing approval in Indonesia for a new pharmaceutical product. The product does not receive patent protection. A local firm decides it would like to market a generic version of the brand-name product in Indonesia. It submits bioequivalence data, and obtains marketing approval, with the Indonesian regulatory authorities relying on their earlier approval of the brand-name product. The brand-name company cannot block the generic from entering the market. The brand-name company provides documentation that it expended \$100 million in clinical tests. The Indonesia generic competitor is required to pay a portion of 0.2% of those costs – \$200,000. Assuming only one generic competitor, the generic firm must pay half of this cost (\$100,000), spread out over a five-year period. So the generic firm’s payment would be \$20,000 annually. If the generic firm entered the market after the brand-name corporation had already been on the market for three years, it would be required to make payments for only two years.

### *3.2 Implementation of the cost-sharing approach*

The USA maintains a version of the cost-sharing approach for agricultural chemical registration, under its Federal Insecticide, Fungicide, Rodenticide Act (FIFRA).<sup>1</sup> Under the US system, pesticides and other agrichemicals receive a ten year period of marketing exclusivity. For the 10-year period afterwards, generic competitors may enter the market based on the cost-sharing approach.

The system works smoothly in the USA. After the expiration of an exclusivity period, generic entrants have an automatic right to use registration data. Disputes over compensation will not delay generic entrance, and are resolved while generic firms are on the market.

When a generic firm enters the market, the parties first seek to reach voluntary agreement over levels of compensation to be paid by the generic entrant. Disputes over the amount of compensation are handled by arbitrators, who conduct fact-intensive hearings that resolve cases much faster than would be achieved through the US court system. Arbitration decisions are final, cannot be appealed and are enforceable.

FIFRA was adopted in 1975, and there is now a fairly significant body of published arbitration decisions relating to implementation of the law, which offers a minimal framework of guidance. These cases turn in part on the specific language of the US statute, but also demonstrate arbitrators' best effort to work out sensible principles to guide the allocation of cost-sharing burdens.

Under the US agrichemical system, compensation is based on the actual costs incurred by the originator of the data in the development of data that is used to obtain registration (Enviro-Chem and Lilly, 1999).

The core of most arbitrated disputes is over which costs incurred by data originators are reasonably part of the registration process (Proem and Grapetek, 1999).

The debate over compensation presumes carefully documented disclosure of originators' specific costs (Avecia and Mareva Piscines Et Filtration's, 2002; Cheminova and Griffin, 2001). Arbitrators generally look skeptically on cost estimates submitted by originators, as opposed to genuinely documented costs (Proem and Grapetek, 1999). Arbitrators typically will reduce estimates, or substitute their own estimation of reasonable costs if no documentation exists (Dowelanco and Albaugh, 1998; Enviro-Chem and Lilly, 1999).

In addition to determining costs, arbitrators frequently consider how to allocate costs, and whether costs should be adjusted.

The allocation of costs issue generally turns on whether a generic entrant should pay an equal portion of the costs of generating the registration data, or whether it should pay a share reflective of its market share. Arbitrators have split over this question, but have trended to allocating cost based on the first of these methods, typically referred to as 'per capita' (Avecia and Mareva Piscines Et Filtration's, 2002; Ciba-Geigy and Drexel Chemical, 1994).

However, arbitrators typically are willing to look at whether reliance and use of the originator's data enables generic entrants to enter all relevant markets. Generic firms are able to rely on the data to obtain marketing approval by US federal authorities. But if they do not obtain actual copies of the data, they are not able to gain marketing approval in certain states – including California and Arizona – which require generics to submit data, not just rely on data in the regulators' file. Where generic firms are not able to enter

these markets, arbitrators are willing to make an adjustment in the amount owed to the data originator (Cheminova and Griffin, 2001; Microgen and Lonza, 2000).

### *3.3 Policy rationale for the cost-sharing approach*

Cost-sharing is a TRIPS-plus approach to TRIPS Article 39.3, but one designed to impose minimal obstacles to generic competition.

It acknowledges that there are genuine and significant costs associated with conducting clinical trials to obtain marketing approval for pharmaceuticals. By providing compensation to companies that originate registration data, the cost-sharing approach deals directly with the claims by brand-name pharmaceutical companies that 'free-riding' by generic entrants will undermine R&D incentives or unfairly situate the originators of registration data.

But the cost-sharing approach narrowly tailors the reward offered to data originators. It provides direct compensation based on the actual cost of data used to obtain marketing approval, ensuring that data originators obtain proportionate compensation for others' use of the results of the originators' investment.

This approach contrasts sharply to the data exclusivity approach, which rewards data originators with effective marketing monopolies (typically for five years or more). The cost-sharing approach considers an effective marketing monopoly as likely to provide overcompensation for data originators, enabling them to earn many times the cost of their investments. The cost-sharing approach also rejects the idea of a marketing monopoly as inappropriate for an investment-based compensatory scheme – one that is trying to avoid uses of the fruits of originators' investment that may be considered 'unfair', but is not trying to reward creative genius in the fashion of patents.

To ensure that cost-sharing compensation is set reasonably, this approach insists that data originators must disclose their actual costs, and provides compensation based on those costs. Generic firms pay a fair share of the costs, proportionate to the national market(s) in which they operate, the number of competitors in that market, and the period they will be using the data during the course of the five years following marketing approval for the originator. Compensation is not provided for pharmaceutical products that are covered by a patent, since the patent monopoly confers sufficient economic opportunity on the data originator to enable the firm to recoup its costs in generating registration data. A well-structured cost-sharing system will also establish that the right to compensation expires after a data originator has earned from product sales a certain multiple (here recommended as 20 times) of its cost in generating registration data. At that point, the data originator will have already recouped its investment from sales, and so does not require additional compensation from generic competitors.

Finally, and crucially, the cost-sharing approach functions as a liability rule. That is, any generic firm retains an automatic right to use or rely on the data generated by a brand-name firm, or to rely on the marketing approval granted based on that data. The only subject of case-by-case negotiation and dispute is the amount of compensation they must pay for use of or reliance on the data, and unresolved questions about compensation are not permitted to stand in the way of a generic using or relying on the data to obtain marketing approval.

There are several potential objections to the cost-sharing approach.

- First, it may be viewed as administratively difficult or complicated. However, potential administrative difficulties are dramatically lessened by establishing an automatic right of generics to use or rely on originators' data. Thus, there is no dispute or litigation over the core issue of whether generic firms have a right to use the data, only over how much they must pay to do so. Moreover, the US experience shows that handling compensation issues is not overly complicated. And the US experience also points to ways to simplify the process of establishing compensation – some now part of US practice, some not. These include: basing compensation on actual and documented costs; resolving by statute or regulation the issue of whether compensation is to be paid proportionate to the national share of the global market; resolving by statute or regulation the issue of whether compensation is to be paid on a market share or equal share ('per capita') basis; resolving by statute or regulation the issue of whether risk adjustments shall be made to actual costs incurred by data generators; and resolving by statute or regulation the issue of whether an early entry penalty shall be applied. All of these matters are resolved simply in the model approach suggested here. Moreover, if administrative difficulties do arise in establishing compensation, the model approach suggested here permits the Ministry of Health to substitute a royalty payment.
- A second objection to the cost-sharing approach may be that it undercompensates brand-name companies that generate registration data. But because the proposal requires generic entrants to pay a proportionate share of generating the data, it is hard to see the basis for such an objection. This is especially so because the approach recommended here suggests inclusion of a risk adjustment, so that data generators are compensated for the possibility of failure. Generic firms gain no unfair advantage, because they are paying the data generators a proportionate share of the costs of potential failure. (Or considered slightly differently, the generics are paying a proportionate share of the real costs brand-name firms incur in conducting clinical tests across a broad spectrum of products, including those that fail and never get to market). The brand-name firms may reasonably be considered as undercompensated under this system only to the extent that they should be paid more than a proportionate share of their full and actual costs in generating data. The cost-sharing approach rejects the claim that they should be so paid.
- A third and contrary objection may be that the cost-sharing approach inappropriately overcompensates brand-name firms, unjustly enriching them and costing consumers who must as a result pay a higher cost for competitive generic products. This argument, implicit in the misappropriation approach, would contend that brand-name companies gain adequate advantage by being the first on market; that corporate development investments routinely benefit competitors and that companies have no special entitlement to compensation for this fact (especially when operating in a field heavily reliant on patents, which do provide for special rewards for genuine inventions); and that, especially in developing countries, the consumer interest in low-priced medicines outweighs the brand-name company claim to compensation for generating data. A related objection is that the cost-sharing approach is TRIPS-plus, and that TRIPS-plus measures should be rejected both on principle and because they delay or raise the cost of generic competition and thereby harm consumers.

A first response to this set of objections is that the actual cost to generic firms of the cost-sharing approach will be modest, especially in smaller market countries.

The cost-sharing approach has the advantage of directly addressing brand-name companies' rationale for data exclusivity, but on terms that do not overly burden consumers. It acknowledges there are real costs to generating clinical test data, and even accepts that generic firms should help shoulder the burden – but at a level fair and proportionate to actually incurred and documented expenses.

Addressing brand-name companies' rationale for data exclusivity is important not only on the merits of those arguments, but as a negotiating position. In bilateral and regional negotiations over free trade agreements and in other discussions, a growing number of developing countries are agreeing to data exclusivity proposals. They are finding that the misappropriation approach is not a viable negotiating posture. This is so despite the fact that the misappropriation approach is well grounded in the TRIPS text and negotiating history. By contrast, the cost-sharing approach can give developing countries something to offer that may undercut demands for data exclusivity by addressing the underlying basis for any claims to reward to brand-name companies for conducting clinical tests.

## **4 A compulsory licensing system for registration data**

### *4.1 Explaining a compulsory licensing system for registration data*

Data exclusivity gives data submitters an absolute right of exclusion to block others from using or relying on the submitters' registration data for a particular period of time. Countries, however, may choose to adopt compulsory licensing procedures for the data – rules that authorise third parties to use or rely on the data, or permit government agencies to use or rely on the data in considering registration submissions from third parties.

Countries adopting compulsory licensing regimes for data exclusivity have a number of choices.

They must determine the grounds for issuing a compulsory licence – in what circumstances should compulsory licences on the data be issued?

They must determine whether compulsory licences should be issued automatically when certain conditions are met or as a matter of discretion.

And they must decide whether compensation will be paid, and in what amount.

The broadest compulsory licensing system would involve the automatic issuance of a licence to use or rely on the data whenever a third party sought to obtain marketing authorisation. Such a system would work like the cost-sharing approach described in Section 5.3, which itself may be considered a compulsory licensing system. This broad approach, featuring an automatic right to use all data, effectively shifts the entire data protection system away from exclusivity to a liability regime.

A compulsory licensing system could also be designed more narrowly, so as to preserve the basic exclusivity approach but to include key exceptions.

For example, the data could be compulsory licensed automatically in cases where a compulsory licence has been issued on an associated patent, or in any case where the registered product incorporates a patented invention. (Such rules would effectively replicate the waivers described in Sections 5.2, though they might conceivably include compensation.)

Registration data might also be compulsorily licensed, either upon application or at the ministry's own initiative, where the Ministry of Health finds that a compulsory licence on the data would advance important public health needs.

In some cases, countries may choose to set compensation for compulsory licensed registration data at zero. For example, if the data is compulsory licensed in conjunction with a compulsory licence on an associated patented pharmaceutical, they may determine that the compensation paid for the compulsory licence on the patent is sufficient remuneration for use of the registration data as well.

In other cases, countries may choose to require a payment of compensation for use of the registration data. This might involve a royalty rate (for example, 2–6% of sales), or compensation based on the disclosed costs of generating the data (similar to the approach in the cost-sharing approach above).

#### *4.2 Implementation of a compulsory licensing system for registration data*

Several countries maintain compulsory licensing systems for registration data. Costa Rica empowers the health authority to issue compulsory licences on registration data to address serious public health problems, in cases where a registered product is not being commercialised, and to remedy anti-competitive practices.

Brazil provides for a compulsory licensing system for registration data on products for which it affords data exclusivity. This system is implemented upon request of third parties, if products are not commercialised in Brazil within two years of registration, or for any reason after three quarters of the data exclusivity period has expired.

Colombia provides for a waiver of data exclusivity if the Ministry of Health determines a waiver is necessary to protect the public, or if a registered product has not been placed on the market in Colombia within one year of registration. This latter waiver is automatic, not requiring a decision of any government agency. Compensation is not required in case either of a waiver to meet health needs or because of lack of commercialisation.

#### *4.3 The rationale for a compulsory licensing system for registration data*

Data exclusivity provides for an effective marketing monopoly for data submitters. The social and health costs of such a marketing monopoly may be very high, resulting in very high prices charged to patients, many of whom may as a result be denied access to needed treatments. Marketing monopolies may result in overcompensation to data submitters. And they may undermine effective functioning of a competitive marketplace.

To mitigate these dangers, countries with data exclusivity regimes should incorporate compulsory licensing regimes for registration data.

The rationale for the broadest such system – the cost-sharing approach – is described in Section 3.3.

Countries that decline to implement the cost-sharing approach should nonetheless adopt compulsory licensing systems to deal with specific cases of abuse with the potential to arise from marketing monopolies. These include

- Compulsory licences for registration data where the associated patented invention has been compulsory licensed. No compensation should be paid in such circumstances, because adequate compensation will have been provided through the compulsory licence. The rationale for such a measure is described in Section 5.2.1; the rationale for a system of compulsory licensing of registration data for patented pharmaceuticals is discussed in Section 5.2.2.
- Where the Minister of Health determines that issuance of a compulsory licence will advance public health purposes, including because the registered product is being made available to the public in insufficient quantity or quality or at prices that prevent people who need the product from obtaining it. Data exclusivity confers an effective marketing monopoly, which means one firm can control access to important drug therapies. Where this contravenes public health needs, the health agency should have authority to override the government-created monopoly and act to meet its duties to protect public health.
- Where the registered product has not been placed on the market, or where necessary to remedy anti-competitive practices. Where a product is not on the market, a licence to use the registration data will be needed to authorise entry of generic firms that will sell the product. And because government-created monopolies can be abused – as monopolies tend to be – the government should retain the right to break the monopoly it has created as a remedy to anti-competitive practices.
- To advance other public interest objectives which might be thwarted by an effective marketing monopoly for pharmaceuticals. One such ground may be that a third party has unsuccessfully endeavoured during a reasonable period of time (e.g., 90 days) to obtain the data submitter's consent for the use of the data under reasonable terms and conditions. In such case, a compulsory license may be issued on the data for the purpose of facilitating competition.

A compulsory licensing system for registration data is TRIPS compatible.

This approach may not be compatible with the data exclusivity requirements of many free trade agreements, which require that data exclusivity be provided to any new pharmaceutical product and do not include exceptions.

## **5 Public health-oriented variants of the data exclusivity approach**

Despite the public health drawbacks of the data exclusivity approach, most industrialised countries and a considerable number of developing countries have adopted this approach. Others remain under pressure to do so, including as part of international trade negotiations.

It thus may be important for countries to consider public health options within the framework of the data exclusivity approach. All of the alternatives considered here are compatible with country obligations under TRIPS Article 39.3. Many are compatible also with the obligations that many countries have accepted as part of bilateral or regional trade agreements.

### *5.1 Restricting the scope of data exclusivity to new chemical entities*

Many new pharmaceutical products do not utilise new chemical entities (NCEs). They may be existing chemical entities reformulated. They may be existing chemical entities sold for a new indication. They may be salts or other derivative versions of existing chemical entities. In general the investment cost for reformulated products, products sold for new indications or derivative products will be less than for NCEs.

Countries may choose to provide data exclusivity not to all new pharmaceutical products, but only to those consisting of NCEs. Egypt follows such an approach.

Restricting data exclusivity to NCEs narrows the class of products to which a marketing monopoly will be provided. It speeds generic competition for a considerable range of products, providing patients with lower prices.

### *5.2 Waiving data exclusivity in certain cases*

#### *5.2.1 Compulsory licensing of patents*

A country may choose to waive its provision of data exclusivity in certain cases. Where it has issued a compulsory licence on pharmaceutical-related patents, it may choose as to waive the data exclusivity for the pharmaceutical.

Almost every country that provides for the granting of patents also provides for compulsory licensing.

Yet the ability to undertake compulsory licensing can be thwarted by data exclusivity.

If a compulsory licence is issued on a pharmaceutical, generic firms are permitted to make, use or sell the invention covered by the compulsory licensed patent or patents.

However, even if there are no patent barriers to entering the market, generic firms must still obtain marketing approval. If a country provides for data exclusivity, the firms will effectively be barred from obtaining marketing approval for as long as the data exclusivity term lasts.

In such an instance, the policy decision made to have issued a compulsory licence, promote competition and improve access to medicines will have been undermined by the second-level of effective monopoly protection conferred by data exclusivity.

The problem can be solved by waiving the data exclusivity protection in case of compulsory licence. Then, automatically upon issuance of a compulsory licence, the data exclusivity problem is eliminated.

The same result can be effected by stipulating that compulsory licences on patents automatically include a compulsory licence of the right to use or rely on the associated data – a proposal discussed in Section 4.

This approach may be incompatible with many free trade agreements, which include strict and unambiguous requirements for the provision of data exclusivity.

#### *5.2.2 Patented products*

The logic of providing data exclusivity is to afford pharmaceutical companies a means to recoup part of the cost of their investment from competitors who will make use of the clinical test results of that investment. But companies with patent protection for their products already gain a marketing monopoly and the ability to recoup that investment. Giving these companies data exclusivity in addition risks overcompensating them – they may be able to effectively extend the marketing monopoly conferred by the patent, or

they may be able to thwart a compulsory licence. To avoid overcompensating patent holders and denying patients access to important medicines, it is appropriate not to provide data exclusivity to products that incorporate a patented invention.

This approach may not be compatible with the data exclusivity requirements of many free trade agreements, which require that data exclusivity be provided to any new pharmaceutical product.

### *5.3 Affecting the term of data exclusivity*

#### *5.3.1 Shortening the term*

While most data exclusivity rules provide a 5–10 year period of exclusivity, this period is an arbitrary one, not correlated to the actual costs of investment in clinical trials. The provision of a marketing monopoly can be extraordinarily profitable; and five years is likely to overcompensate data originators. A country providing for data exclusivity should thus consider shortening the term to, say, three years, or indeed any length it chooses.

Such a system would still confer data exclusivity's effective marketing monopoly on the data originator, but for a shorter term.

#### *5.3.2 Adjusting the start date of data exclusivity*

Pharmaceutical companies frequently do not introduce a product in all national markets at the same time. If the period of data exclusivity commences when a product gains market authorisation in country X, but marketing authorisation was obtained two years after it was obtained in country Y, then the data exclusivity-conferred marketing monopoly will continue in country X for two years after it starts in country Y.

A country may start its period of data exclusivity by reference to the first worldwide registration of the product.

This will help ensure that consumers in smaller market countries – where brand-name companies may register their products later than in larger markets – are not forced to wait extra time for finalisation of the data exclusivity period. It also provides an incentive for pharmaceutical companies to register their products more quickly in smaller markets, so that their marketing monopoly in those countries lasts longer.

Some free trade agreements specify that the start date for data exclusivity in a country must be when marketing authorisation is first granted in that country.<sup>3</sup> For countries that are members of these trade agreements, adjusting the start date for data exclusivity is not an option.

## **6 Conclusion**

In implementing TRIPS Article 39.3, countries should be aware of the broad range of flexibilities available to them, and the public health costs of pursuing certain implementation approaches.

The misappropriation approach is TRIPS compliant and imposes the smallest barriers to generic entry and the lowest cost on consumers.

Countries that choose not to adopt the misappropriation approach, because of concern about supporting R&D, fairness to data generators, or pressure in international trade negotiations, should give strong consideration to the cost-sharing approach. This approach satisfies the substantive rationale for data exclusivity, while tailoring the compensation paid to data originators to assure they are not overcompensated. It is simple to administer and will impose only very modest barriers to generic entry and minimal costs on consumers. For these reasons, countries that are not able to defend a misappropriation approach in trade negotiations and are being pressured to agree to a data exclusivity regime should counterpropose a cost-sharing system.

Countries that choose to employ a data exclusivity system will effectively preclude generic competition during the period of data exclusivity. This will impose high costs on consumers, who will either be required to pay higher prices than would be obtained with generic competition, or will be unable to afford needed medicines altogether. Especially because there is an alternative and less costly system – the cost-sharing approach – which satisfies the policy rationale for data exclusivity, countries should be very cautious before adopting a data exclusivity regime.

Those that do adopt a data exclusivity system should limit its scope by specifying that data exclusivity is provided only to new chemical entities and for undisclosed information.

Most importantly, they should specify that data exclusivity is waived in cases of compulsory licensing of associated patents (or that registration data is automatically compulsory licensed along with a compulsory licence on the associated patents). Failure to adopt such measures will mean that data exclusivity will thwart governmental efforts to issue compulsory licences on medicines, for the term of the data exclusivity.

A second top priority for countries maintaining data exclusivity systems should be to maintain a general compulsory licensing system for data, so that policymakers have latitude when needed to issue licences and create exceptions to the effective marketing monopolies conferred by data exclusivity. They should have such authority at least in cases to meet public health needs and to remedy anti-competitive practices.

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## Notes

<sup>1</sup>Section 3(c)(2)(B), 7 U.S.C. 136a(c) (2) (B), of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. §§136-136y.

<sup>2</sup>Developed and drafted with James Love.

<sup>3</sup>See, for example, the USA-Central American Free Trade Agreement, Article 15.10.1(a).