

The GIPC IP Report 2014: Hammering in a Screw

Critically reviewing the GIPC International IP Index, 2014

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The GIPC Report: Hammering in a screw

The US Chamber of Commerce's Global Intellectual Property Center (GIPC) recently published the 2nd edition of its IP Index. The GIPC Index undertakes a commendable task of quantifying the development of different IP regimes around the world. A well functioning IP system is crucial for innovation, and it is innovation, along with the spread of the resulting knowledge that stimulates economic growth, development and job creation. A focus on innovation is therefore a must for all national governments.

This year's edition of the GIPC IP Index has increased the number of its indicators from 25 to 30 and has also increased the number of countries studied from 11 to 25. However, it's unfortunate to see that IP hasn't been appreciated for the complicated, nuanced area that it is. Further, the index seems to have erroneously focused on IP as an end in itself rather than focusing on IP as a means towards innovation. Such an approach is fraught with many dangers as there is no questioning that IP systems require intelligent safeguards and regulations to ensure they are not misused.

An example within the US is the proliferation of non-practicing entity (NPE) litigation. A 2012 study of 82 firms, who mounted 1184 defences against NPE litigation in 2011, estimated that the direct costs accrued from NPE action in that year was \$29 billion, up 400% from the 2005 figure of \$7 billion.¹ 82% of the defendants were small and medium sized companies. Shortly before the publication of the GIPC Index, the US House of Representatives, in an effort to

¹ James Bessen, Jennifer Ford, and Michael J. Meurer, *The Private and Social Costs of Patent Trolls*, Boston University School of Law (Winter 2011-2012) <http://www.bu.edu/law/faculty/scholarship/workingpapers/documents/Bessen-Ford-Meurer-no-11-45rev.pdf> (Last viewed on 6 February 2014).

address the tremendous losses caused by NPE litigation passed the “Innovation Act”² which attempts to combat patent abuse.

It’s strange to note that the GIPC Index does not make any mention of this economy draining NPE litigation nor of the attempts to counter the problem. Nonetheless, the larger point remains that Intellectual Property remains a vital part of innovation and innovative activity, only so long as appropriate safeguards are taken into account for its nuanced and complicated nature.

As the GIPC report rightly notes, countries at different levels of development are affected differently by intellectual property regimes. The index itself however does not account for these differences, with the same baselines for all 30 indicators being used for rich and poor countries alike. It further claims that the scoring methodology allows countries to be compared on a ‘like for like’ basis. This is an over-simplified approach that contradicts the understanding that IP is a means, not an end – and that countries are affected in different ways by intellectual property regimes. This approach also is in direct opposition to the World Intellectual Property Organization (WIPO)’s development agenda, which categorically asserts that IP regimes must be calibrated according to the ‘development’ quotient of the country in question. Approaching IP as a blunt instrument is akin to using a hammer even where a screwdriver is needed – it destroys the wall and the screw. IP regimes must be carefully crafted to ensure that they remain drivers of innovation and do not become blunt instruments that allow monopolies regardless of the costs. A closer look at the indicators also raises questions as to why certain indicators are present at all. Before any IP index is used by analysts, policymakers and governments, it must stand up to

² [H.R.3309](http://thomas.loc.gov/cgi-bin/bdquery/z?d113:h.r.3309), 113th Congress (2013-2014), available at <http://thomas.loc.gov/cgi-bin/bdquery/z?d113:h.r.3309>: (Last viewed on 6 February 2014).

scrutiny if it is to be successfully used to tailor IP regimes to best increase innovation globally.

This report offers critical commentary on the methodology, baselines and indicators used in the GIPC report. The review will be done so in the context of pharmaceutical innovation specifically, although broader issues will also be mentioned alongside.

Selection of Countries

The GIPC Index examines eleven high-income countries, nine upper middle income countries and five lower-middle income countries. Conspicuous by their absence are Switzerland, Sweden and Germany – countries well known for their innovative capacity. Switzerland and Sweden have in fact been at the top of the Global Innovation Index (GII) for two years running now. The Global Innovation Index, an annual index maintained by WIPO, INSEAD and Cornell University since 2007, uses 84 indicators to look at 142 economies around the world, ranking them according to their innovative capacities.³ Though the GIPC report uses only about one third of the indicators and focuses only on the IP portion of innovation, it is still surprising to note the contrast amongst the relative ranks of the 25 countries studied by the GIPC index. The table listed below gives more details.

³ <http://www.globalinnovationindex.org/> (Last viewed on 6 February 2014).

Table 1: Country rankings GII v. GIPC

	Country	GIPC Rank	GII Rank	GIPC Countries ranked in GII order
	United States (US)	1	5	2
	United Kingdom (UK)	2	3	1
	France	3	20	7
	Singapore	4	8	3
	Australia	5	19	6
	Japan	6	22	8
	New Zealand	7	17	5
	Canada	8	11	4
	Malaysia	9	32	9
	Mexico	10	63	18
	Colombia	11	60	16
	Chile	12	46	12
	Russia	13	62	17
	Turkey	14	68	21
	United Arab Emirates (UAE)	15	38	11
	Ukraine	16	71	22
	China	17	35	10
	South Africa	18	58	15
	Brazil	19	64	19
	Nigeria	20	120	25
	Argentina	21	56	13
	Indonesia	22	85	24
	Vietnam	23	76	23
	Thailand	24	57	14
	India	25	66	20

Table 2: Distribution of countries in terms of income

High Income Countries (11)	Upper Middle Income Countries (9)	Lower Middle Income Countries (5)
Australia, Canada, Chile, France, Japan, New Zealand, Russia, Singapore, United Arab Emirates, United Kingdom, United States of America	Argentina, Brazil, China, Colombia, Malaysia, Mexico, South Africa, Thailand, Turkey	Indonesia, India, Nigeria, Ukraine, Vietnam

Though the number of countries included in the index has dramatically risen since the 1st edition, a better balance of countries would serve the index well. Currently there are only five countries in the lower middle-income (LMI) group, as opposed to twenty countries in the income ranges above LMI. This imbalance in the representation of upper/middle income and lower middle-income countries seriously undermines the soundness of the index’s comparative ranking methodology. This is especially acute in the discussion on the positions of countries on the LMI range where the index, unfortunately, lends itself more to rhetoric than being analytically instructive. A further nuance, which an advance index would capture, is the understanding that certain countries, such as India, while “developed” in certain technology sectors are still considered “developing” for the most part, owing to a large percentage of their population still below the poverty line. They have been labeled as “technology proficient developing countries”.⁴

⁴ Basheer, Shamnad and Primi, Annalisa, The WIPO Development Agenda: Factoring in the ‘Technologically Proficient’ Developing Countries (October 19, 2008). IMPLEMENTING WIPO’S DEVELOPMENT AGENDA, Jeremy DeBeer, ed., Wilfred Laurier University Press, 2009. Available at SSRN: <http://ssrn.com/abstract=1289288>

It is also worth inquiring into the vast differences of rank even amongst these 25 countries when compared against their respective ranks in the 84-indicator Global Innovation Index. The index does in fact note⁵ that comparing countries is not as ‘statistically robust’ as regression analysis and statistical modeling but uses the comparison regardless. It also unfortunately found it fit to use admittedly ‘less statistically robust’ country comparison data in its press release as a major highlight of the report.⁶

Review of the Indicators and Baselines Used

30 indicators spread out over 6 categories have been used for the GIPC Index with varying baselines values for each indicator. The values given while scoring are of three types: binary, numerical, and mixed. Binary scores are either 1 or 0, depending on whether a particular IP component exists or not. Numerical scores are based on a quantitative source and use baseline values as a denominator. Mixed scores are used when the above two cannot be used, and are given based on the existence of legislation as well as the application and enforcement of that legislation. The scores can be 0, 0.25, 0.5, 0.75, and 1. As per the index, these baseline values are based on

“terms of protection, enforcement mechanisms (de jure and de facto), and/or model pieces of legislations that can be found at the national, supranational, and international level. Where no adequate baselines are found in international law or treaties, the baseline values are based on what rights holders view as an appropriate environment and level of protection”.

⁵ Page 9 of the GIPC report.

⁶ http://www.theglobalipcenter.com/wp-content/uploads/2014/01/021211_GIPC_ChartingFlyer_final.pdf (Last viewed on 6 February 2014).

A hugely problematic methodology of the report is that where no adequate baselines are found in international law or treaties, baselines and values used are based on what rights holders view as an appropriate environment and level of protection. This creates a *prima facie* bias in analysis as well as outcomes of the report. The TRIPS Agreement, with 159 Member State signatories is the determinative international framework governing intellectual property law around the globe. The objectives as provided in Article 7 of the TRIPS Agreement clearly stress a balanced approach in stating that “the protection and enforcement of intellectual property rights should contribute ... to a mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare.” Article 8 gives the principles underlying TRIPS and expressly states that countries, in formulating their laws, can “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development” thereby underscoring the importance of these principles and objectives for intellectual property regimes. To view international intellectual property legislations as mere “right holder” instruments without concern for other imperatives such as public interest and the interest of competitors that such regimes typically seek to envisage, is highly problematic to say the least. This type of an approach casts serious doubt on the integrity of such a report.

As will be seen below, these indicators as well as baseline values, that form the spine of the index, have been haphazardly determined regardless of international obligations and without an understanding of the incentive structures that patents build.

1.1 Patents, Related Rights, and Limitations

Perhaps of most economic significance amongst the three main types of IP, this category includes 7 indicators. They are (1) Patent term protection, (2) Patentability requirements, (3) Patentability of computer-implemented inventions, (4) pharmaceutical-related patent enforcement and resolution mechanism, (5) legislative criteria and use of compulsory licensing of patented products and technologies, (6) patent term restoration for pharmaceutical products, and (7) regulatory data protection.

It is not clear why pharmaceuticals have been given special significance over all other kinds of technology. It would appear that the entire ranking and methodology was devised in order to produce a predetermined set of results.

In the context of pharmaceuticals, all indicators except no.3 are relevant. To understand the import of these indicators, it is relevant to look to the TRIPS Agreement, as the primary international agreement that introduced substantive IP provisions for its member states. The objectives of the TRIPS Agreement, as provided for in Article 7 of the Agreement are that, "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." With this as a background context, the relevant indicators will now be examined.

Indicator (1): Patent term protections

“Measured by the basic patent term offered in the TRIPS Agreement. This is a numerical indicator.”

The baseline value of 20 years used in this indicator is the international norm as per the TRIPS Agreement⁷ and poses no issue.

Indicator (2): Patentability requirements

“The extent to which patentability requirements are in line with international standards of novelty, inventive step, and industrial applicability. Measured by (1) existing *de jure* patentability guidelines and regulations and (2) *de facto* standards established through the application of these guidelines and regulations through the examination process and judicial review. This is a mixed indicator.”

Article 27 of the TRIPS Agreement calls for the introduction of a minimum of 20 years of patent protection for inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to certain conditions, it also states that patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. The extension to all fields of technology is significant, as, prior to the TRIPS Agreement, nearly 50 countries did not provide for patenting of pharmaceuticals.⁸ The question with respect to this indicator, is whether an anti-evergreening provision such as Section 3(d) of the Indian Patents Act, 1970 violates the patentability requirement as per TRIPS. Whether this provision is a separate fourth criteria is also contestable, as a product which does not

⁷ Article 33, TRIPS Agreement.

⁸ See CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 11 (2000) (citing UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT, THE TRIPS AGREEMENT AND DEVELOPING COUNTRIES, 1996), available at: <http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf> (Last viewed on 6 February 2014).

demonstrate sufficient inventive step is not necessarily an ‘invention’ in the first place, and Article 27 expressly mandates protection only to “inventions”

Firstly, a factually incorrect statement in the GIPC India report will be clarified below:

“Specifically, as per the Supreme Court of India’s ruling on April 1, 2013, in the Novartis Glivec case, Section 3(d) can only be fulfilled if the patent applicant can show that the subject matter of the patent application has a better therapeutic efficacy compared with the structurally closest compound as published before the patent application had been filed (regardless of whether or not a patent application on the earlier compound was filed in India).”

The Supreme Court’s ruling in the Novartis Glivec case held that Section 3(d) requires that a new form of a known substance (as opposed to the structurally closest compound), shows better therapeutic efficacy if it is to be patented. The framing of the sentence would seem to indicate that the bracketed portion is significant. However, it is standard practice in patent offices world over, for prior art, whether due to being in the public domain or disclosed in a previous patent application, to be used while determining the novelty of a product.

The Novartis Glivec case is also a strange case to rely upon, as in the case, Novartis only submitted information regarding increased bioavailability of the beta crystalline form of Imatinib Mesylate over the Imatinib free base, rather than showing how, if at all, that bioavailability resulted in increased efficacy. The Court also specifically stated that increased bioavailability could lead to better therapeutic efficacy, though, naturally proof would need to be given to indicate the same.

Secondly, the bigger question of whether such a provision violates TRIPS needs to be answered.

The TRIPS Agreement puts in place certain safeguards against the abuse of intellectual property rights. As stated earlier, Article 7 which lays out the objectives of the Agreement, emphasizes that the protection of IPRs should ‘contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.’ As per the “Principles” provided for in Article 8, a Member State’s right to legislative enactments protecting public health and nutrition is recognized, provided such measures are consistent with the provisions of the Agreement. The 2001 Doha Declaration on the TRIPS Agreement and Public Health⁹ further recognized and reaffirmed nations’ rights to protect public health.

It is in this context that ‘weak’ or ‘bad’ patents ought to be looked at. Weak patents are those which are insufficiently inventive, or trivial, or are otherwise lax and can result in the blocking of legitimate innovation, discouraging further innovation, market distortions, and harm for public welfare, all while allowing monopolistic exclusion rights over the ‘badly’ patented product. Any provision of any act which looks to cut down on these bad patents, would clearly not only be non-violative of TRIPS but in fact would be supporting the framework and objectives of TRIPS as well as the existence of any useful IP regime.

Indeed, the presence of novelty, non-obviousness and utility as minimum patentability requirements are designed to prevent exactly this. Pharmaceuticals, however, present a specific problem that is not present in other areas. Chemical

⁹ WT/MIN(01)/DEC/W/2 (2001) [hereinafter Doha declaration].

entities can often have multiple forms, achievable through known chemical processes. It is not viable/practical to test out all the forms each time a new form is created, however a person who is reasonably skilled in the art can often predict the specific properties that a change in form of a substance will have. This allows for the filing of a patent over a known substance, and then with some slight modifications in form near the end of the patent period, allows the patentee to apply for another patent over a product which is of little improvement, if at all, over the previously patented product. Preventing this type of activity is referred to as the prevention of ever-greening. This is in line with the US Federal Circuit Court's opinion in *Pfizer v. Apotex*,¹⁰ wherein the Court invalidated Pfizer's drug Norsvasc, by finding that the claimed advantage (better solubility and stability) was fairly ordinary and the result of mere routine experimentation.

It is once again worth noting that the term "invention" has not been defined, leaving open the possibility of barring products which are not 'inventive' from coming under the scope of "inventions" which require protection as per TRIPS.

Looking into the wording of Article 27, the question then arises as to whether pharmaceuticals are being discriminated against by a provision directed at chemical products. The Panel as constituted under the WTO dispute settlement understanding, in *Canada - Patent Protection of Pharmaceutical Products*,¹¹ described the meaning of the term 'discrimination' as "results of the unjustified imposition of differentially disadvantageous treatment." The Panel also noted that Article 27 does not prohibit bona fide exceptions to provisions that address problems that exist only in certain areas. Therefore a provision that recognizes and attempts to address a significant problem specific to a field of technology can be said to impose 'differential treatment' but certainly not 'differentially

¹⁰ No. 2006-1261 (Fed. Cir. 2007)

¹¹ Canada - Patent Protection of Pharmaceutical Products, Report of the Panel, WT/DS/114/R

disadvantageous treatment'. Such a position, recognizing the TRIPS compatibility of anti evergreening provisions such as Section 3(d) of the Indian Patents Act, 1970 is well supported by leading IP academics as well.¹²

Thus, not only does an anti-evergreening provision such as Section 3(d) not violate international norms but in fact supports and furthers the goals of TRIPS as envisaged by its objectives and principles. Yet, the indicator falsely implicates this as a problematic development.

Indicator (4): Pharmaceutical-related patent enforcement and resolution mechanism

“Measured by the existence of primary and/or secondary legislation (such as a regulatory mechanism) that provides a transparent pathway for adjudication of patent validity and infringing issues before the marketing of a generic or biosimilar product. This score is evenly divided between the existence of relevant primary and/or secondary legislation and its application/enforcement. If no legislation is in place, the maximum score that can be achieved is 0.5 based on the extent to which *de facto* practices are in place that achieve a similar result. This is a mixed indicator. “

While the previously discussed indicator held India liable for treating pharmaceuticals differently, this indicator seems to hold India liable for not

¹² See for example, Basheer, Shamnad and Reddy, Prashant, 'Ducking' TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d) (January 17, 2009). National Law School of India Review, Vol. 20, No. 2, pp. 131-155, 2008. Available at SSRN: <http://ssrn.com/abstract=1329201>; Kapczynski, Amy,; Harmonization and its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector, 97 Calif. L. Rev. 1571 (2009); Linda Lee, *Trials and TRIPS-ulations: Indian Patent Law and Novartis AG v. Union of India* 23(1) Berkeley Tech. L.J. 281 (2008); V. K Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health* 25(1) Pac. McGeorge Global Bus. & Dev. L.J. 323 (2012)

treating pharmaceuticals differently. There is certainly nothing in any international IP norm that indicates pharmaceutical-related patent enforcement and resolution mechanisms are to be treated any different from patent enforcement and resolution mechanisms of any other sector. In fact, TRIPS itself states that if the existing general enforcement machinery is robust, then no special enforcement machinery need be put in place for IP. Nonetheless, given that pharmaceutical specific legislation, as described above, is legitimate, it may make sense to track pharmaceutical specific enforcement and resolution mechanisms as well.

As per the index, this score is evenly divided between the existence of relevant primary or secondary legislation, and its application/enforcement. On examining the country reports though, this baseline for this indicator seems to be whether patent-linkage legislations/provisions exist in the country or not, and whether such legislations are enforced. Patent linkage refers to linking the marketing approval of a drug with its patent validity. Patent linkage however assumes that the drug regulator is competent, legally and institutionally, to determine whether an application for drug approval may violate an existing patent. The drug regulator's job is simply to test whether a drug is safe and efficacious for public use. Imposing the additional burden of determining patent validity is impractical, especially in developing countries where resources are already scarce. Patent linkage is also in opposition to the spirit of research exemptions, also known as Bolar exemptions. Bolar exemptions minimize delay in the launch of generics by allowing the drug to be ready to launch with regulatory approval as soon the expiration or invalidation of the patent, rather than wait for the lengthy proceedings to start only after the patent has expired. Patent linkage claims have also been turned down by Courts in India. In Bayer

Corporation v. Union of India¹³ the Delhi High Court pointed out that patent rights were negative rights that could only be protected only by resorting to the framework under the Patents Act. It also held that patent linkages is a TRIPS plus concept and was not required to be implemented.¹⁴

On a more general note however, if this indicator is used properly with a clearly specified baseline that does not include patent linkage, this indicator could prove to be very useful in determining which countries have trouble enforcing their pharmaceutical patents. It is to be noted though, that a court's decision which rights-holders dislike, is not necessarily one that indicates there is a problem with patent enforcement. As stated earlier, an IP regime that does not allow weak patents is beneficial for society. The strength of "enforcement" cannot be measured solely by how IP owner friendly it is, but also whether the enforcement adequately balances out the interests of competitors and the general public.

Indicator (5): Legislative criteria and use of compulsory licensing of patented products and technologies

"Measured by the extent to which primary and/or secondary legislation on the use of compulsory licensing and its application/enforcement is transparent and consistent with the following criteria:

- (1) the issuing should exclude any requirement for domestic manufacturing;**
- (2) the issuing should not apply to patented innovations that have not yet reached the market;**
- (3) in the case of biopharmaceutical products, the use of compulsory licensing under the framework of TRIPS provisions on public health should not be for**

¹³ 2010(43)PTC12(Del)

¹⁴ See also Brook K Baker, Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage, 34 Am. J.L. & Med. 303 (2008)

commercial purposes, such as for price negotiations or in support of domestic industries; and

(4) adequate and well-defined recourse mechanisms should be in place for parties affected by the issuing of the license.

This is a binary indicator.”

The indicator on compulsory licensing is based on four baselines. Of these, only one of them is an Article 31 requirement under TRIPS – the existence of a mechanism for judicial review or an independent review by a higher authority of the legal validity of the grant of a compulsory license listed in clause (i) of Article 31.

Baseline (2) and (3) both refer to grounds for the issue of a compulsory license. Under TRIPS, countries are free to determine the grounds on the basis of which compulsory licenses can be given, as long as the safeguards against excessive compulsory licensing as provided in Article 31 are incorporated in domestic law.¹⁵ Thus, there is no justification for the use of these grounds as baselines in measuring the strength of an intellectual property rights system. Further the grounds deemed as illegitimate by the indicator are in fact well-established grounds in international and domestic intellectual property law.

- a. Baseline (2) mentions the insulation of patents that have “not yet reached that market” from compulsory licenses. This is a vague phrase that can have two meanings. The first is that the patented invention has not even been released into the market in that country. In case the compulsory license is sought within the first three years of the grant of the patent, this

¹⁵ World Trade Organization, Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001, WT/MIN(01)/DEC/2, at para. 4, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm [‘Doha Declaration’]; A HANDBOOK ON THE WTO TRIPS AGREEMENT 112 (Antony Taubman, et. al, eds. 2012).

would be in violation of the international norm of requiring three years between the grant of a patent before a compulsory license application for the same can be made and is a valid consideration. However, the other meaning is that the patent has not been adequately worked on a commercial scale. Disallowing a compulsory license on this ground would be a direct contradiction of the Paris Convention (as incorporated by the TRIPS Agreement) wherein the failure to work a patent is a clear ground for a compulsory license and even listed as illustrative of the 'abuse' of the exclusionary rights by a patentee.¹⁶ Non-working and inadequate supply of a patented invention is a ground for a compulsory license in a large number of developed and developing countries.¹⁷

- b. Baseline (3) talks about the use of compulsory licenses for the purposes of negotiating changes in pricing and for supporting the domestic market under the framework of public health. This seems to treat purposefully misinterpret the method in which compulsory licenses are granted. By indicating that compulsory licenses can be used to negotiate prices, it builds a strawman. There are grounds on which compulsory licenses can be granted which are included so as to safeguard against the abuse of patents or be used in times of emergency, etc. Within the framework of public health, the Doha Convention unequivocally states that TRIPS should be interpreted and implemented in a manner particularly supportive of access to medicines.¹⁸ If the patent holder is not abusing the

¹⁶ 5(A)(2)(3) of the Paris Convention for the Protection of Industrial Property

¹⁷ Carlos Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, at p. 12, available at

http://www.iatp.org/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf (Last viewed on 6 February 2014).; A 2009 research finds that this ground is present in the national legislations of 39 out of 41 prominent developing countries. CAROLYN DEERE, *THE IMPLEMENTATION GAME: THE TRIPS AGREEMENT AND GLOBAL POLITICS OF INTELLECTUAL PROPERTY REFORM IN DEVELOPING COUNTRIES* 83 (2009).

¹⁸ Doha Declaration at paragraph 4; Frederick Abbot, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5(2) *JOURNAL OF INT'L ECO. LAW* 469 (2002)

patent, there is no worry for a compulsory license and thus the ‘threat’ of a compulsory license cannot be used to negotiate prices. Similarly, the grounds for a compulsory license do not include the grounds of improving a domestic industry and it would clearly be a violation of international norm if this were allowed as a ground for compulsory licensing. However, this is in clear distinction from a domestic company benefitting as a side-effect of a compulsory license. The presence of a robust generic industry cannot be grounds for disallowing a compulsory license.

- c. Clause (1) can be strongly argued for as per the non discrimination obligation in Article 27.1 of TRIPS. However, as explained, even this standard only prohibits unjustified discrimination and must be read in harmony with the Paris Convention which clearly provides that “importation” would not amount to “working” of a patent, and that if a patent wasn’t worked this could be treated as an “abuse” and would be a ground for the issue of a compulsory license. Article 7 of TRIPS, with its focus of right holders exclusion rights along with the objective of transferring and disseminating technology come into the picture as well. Similarly, Article 8 which allows countries to take measures to prevent the “abuse” of patents which adversely affect the international transfer of technology.

Other problems with the indicator:

The indicator uses a binary method of scoring and is only 1 of 2 indicators, out of a total of 30, to use this scoring method. The binary method allows a score of either 1 or 0 only. The indicator, therefore, is inherently flawed and a wrong reflection of the strength of an IP regime, since the absence of any one of the four baselines would lead to an automatic 0. Thus, it has the effect of treating each

baseline as if it were a prohibited ground in international IP law, which we have already seen, has no legitimate basis.

Finally, in the India specific analysis it lists as a weakness the “Use of compulsory licensing for commercial and non-emergency situations”. This is permitted by TRIPS, as provided for in Article 31 of Agreement and hence cannot be considered as a weakness of its system.

The next two indicators will be dealt with together as they involve overlapping issues.

Indicator (6): Patent Term restoration for Pharmaceutical product

“[T]his protection is aimed at restoring a portion of the patent term granted to innovative pharmaceutical products that is lost, due to the prolonged research, development, and regulatory approval periods of such products”¹⁹.

The baseline used for this is five years, as used by the United States and the EU.

Indicator (7): Regulatory data protection (RDP) term

“Measured by the optimal desired term, which is the term of exclusivity used by the European Union for new biopharmaceutical products containing new active ingredients regardless of molecular size and/or complexity.²⁰ This is a numerical indicator.”

¹⁹ Page 21 of the GIPC Report.

²⁰ Half (0.5) of the available score is based on the term available for biologics or large molecule compounds. If a country’s relevant legislation/regulation either de jure or de facto does not cover such compounds, then the maximum score that can be achieved in this indicator is 0.5. The baseline numerical term used is that by the EU of 10 years (8 years plus 2 years) of marketing exclusivity.

On the face of it, indicator (5) appears to be a very useful indicator as it allows a view of countries that understand the value of patent rights and ensure patent durations aren't affected by delays further up the drug development process. It is to be noted though, that this criterion is not required by the TRIPS Agreement and is what is known as a "TRIPS plus" criterion. There is also no reason given as to why 5 years is taken as the baseline for this criterion. Indicator (6) is more controversial with regards to its TRIPS compliance, with the presence of arguments claiming that TRIPS requires it as well as arguments claiming that it is a TRIPS plus mechanism. However, two points are to be noted:

1. Neither indicator is backed by an international IP norm.
2. Both indicators refer to methods of ensuring that innovator companies have sufficient incentives to bring new products to the market. This is the context in which the baseline value is to be judged.

In the light of the absence of an international norm for this criteria, the index must provide an explanation as to why an international norm is absent for these before putting forward their own alternatives along with reasons for those alternatives.

This brings into play, the interesting question of what the baseline ought to be. As is well known, exclusion periods such as patent duration, are periods during which the patentee can exclude anyone else from making their product. When exclusion periods are granted, they allow the creation of artificially monopolistic prices. These prices are deemed necessary as they serve as incentives for the innovator, who would otherwise not be able to reap rewards on the innovation he is bringing to the market. This arrangement is beneficial to society so long as the innovation is worth the costs incurred by allowing monopolistic behaviour in the market. After a certain duration, it is no longer beneficial for a State to allow

an exclusion period, since, as is the case with any anti-competitive monopoly, the State starts incurring more costs than benefits by granting such exclusion periods. This is the reason a limited period of exclusionary rights is granted to patent holders rather than an indefinite period. By the same measure, 'sufficient' exclusion periods need to be granted so as to ensure that innovation is brought to the market quickly. Thus there is clearly a balance that policy makers need to address while setting such durations.

Back in 1967, William Nordhaus showed that the optimal patent period depends on various factors including elasticity of demand, importance of the invention, etc.²¹ For reasons of efficacy, it is considered desirable to have a standard duration rather than to have varying sector-specific patent durations. However, by the same note, if a specific sector is looking to have an extended patent duration, or an added period of exclusionary rights, it is necessary to understand the effects that such duration may have. It is clear that it will add to the incentives of pharmaceutical companies. It is not clear whether those incentives are required and whether they will lead to unnecessary costs for the rest of society. Costs in the healthcare context equates to death and disease.

A rough estimate of the required exclusionary period required to provide sufficient incentives could be arrived at by comparing the aggregate sales of the pharmaceutical industry with the aggregate costs of the pharmaceutical industry, as held against the currently present patent duration period. However, this would require pharmaceutical companies to share their actual costs which they currently do not do. Estimates on the costs of a new drug range from \$250 million to around \$1.3 billion.²² To take a high profile example, the Glivec patent

²¹. See William D. Nordhaus, *The Optimal Life of a Patent* (Cowles Foundation for Research in Economics Working Paper No. 241, 1967).

²². See Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 165, 180-83 (2003) (estimating a total R&D cost per drug of \$802 million, and

which was so widely discussed in context of the Supreme Court of India's revocation, was estimated to have come about after an investment of about \$96 million dollars.²³ Novartis' sales for Glivec however were about \$4.7 billion dollars in 2012 alone. It is clear that any further exclusion period on this drug would incur massive costs for societies as it would not only block further innovation but also would price out several patients who require the drug

Of course, Glivec is just one example and it is equally true that some drugs are much more costly to develop. The larger point remains that there must be more certainty on this account before any baseline is chosen; otherwise government policy makers relying on this baseline would be putting their respective populace at grave risk of incurring unnecessary costs. This once again brings us to the clearly unbalanced nature of an index that defaults to a rights holders perspective when an international norm is not present.

1.2 Other Problematic Indicators

A casual glance at the other indicators present in the index adds further discredit to the index. For example:

Indicator (8): Copyrights (and related rights) term of protection

“Measured by the baseline term of protection, which is the minimum term afforded in the United States of 95 years. Terms of protection are measured as the minimum term allowed by copyright law. Where there are different

clinical trial costs of \$467 million per drug). For a critique of DiMasi's paper as a gross overestimation, see Donald W. Light, Misleading Congress About Drug Development, 32 J. HEALTH POL. POL'Y & L. 895, 896-900 (2007).

²³ See James Love, R&D costs for Gleevec., KNOWLEDGE ECOLOGY INTERNATIONAL (3 April 2013) available at <http://www.keionline.org/node/1697> (Last viewed on 6 February 2014).

minimum terms of protection for different forms of copyright, all terms are added together and divided by 95. This is a numerical indicator.”

This is problematic on two grounds:

(a) This is not the term afforded by the United States. The United States offers life of author plus 70 years as a general rule. Only for cases of anonymous work, pseudonymous work, or work for hire does the copyright term endure for 95 years from first publication, or 120 years from creation, whichever is shorter .²⁴ Disregarding the scoring methodology they have described above, the index has given the United States a 1/1 score on this indicator, thus indicating that they wrongly believe all works in United States are granted a term of 95 years, or that they have used 95 as well as 120 in their calculations (along with 70), even though they are for the same category of works.

(b) The international norm for copyright durations is 50 years after the death of the author, as provided for in Article 12 of the TRIPS Agreement. Most countries in the world have a duration of between 50 to 70 years after the death of the author. Thus the index is using a baseline value that has no legitimacy in international law and is nearly double the current international norm.

Indicator (15): Non-discrimination/non-restrictions on the use of brands in packaging of different products.

“Measured by the extent to which different national laws and regulations do not unreasonably limit the rights holder from using or putting his brand on the package of his or her products, thereby curtailing his or her rights under trademark protection. This is a binary indicator.”

²⁴ Section 302 of the Copyright Act of 1976, Pub. L. No. 94-553, 90 Stat. 2541

This is one of only two indicators of the 30 that are binary indicators. Like the other one (indicator 5), there is little to no reason for this to be a binary indicator. In fact, only two countries get a 0 on this indicator. They are Australia and Turkey. Both countries have introduced plain packaging requirements for tobacco related products as the only restrictions they have placed on any sort of trademark protection in their respective jurisdictions. Both countries also placed this restriction based on a policy of furthering public health policy. Having a binary indicator in the trademarks sector which is strife with all types of goods is statistically and analytically very poor methodology. The only purpose of this indicator seems to be to send a message to Turkey and Australia for allowing plain packaging of tobacco products.

Indicator 30: At least one free trade agreement with substantive and/or specific IP provisions such as chapters on IP and separate provisions on IP rights provided it was signed after WTO/TRIPS membership—This is a mixed indicator.

The presence of this indicator requires an explanation. Any substantial IP provision that is imported due to any bilateral / multilateral agreement is already scored by the 29 previous indicators. Therefore the addition of this indicator becomes completely redundant and distorts the index. Once again, this points to a flawed methodology.

Conclusion

The presence of an analytically sound and instructive international IP index would be of great use to policy makers and governments in determining optimal IP rights and in understanding the policy levers used to further innovation.

Unfortunately, the GIPC index seems brittle in the face of critique with unsound methodology, questionable indicators and biased baseline values. The critiques presented in this report can be summed up in three categories:

- With only 5 LMI countries out of 25 countries, in a study on IP rights, which affect countries of different levels of development differently, the index presents an unfair bias against lower income countries. These countries are judged against standards which may be optimal for high-income countries but not low-income countries, despite such countries having no international or legal obligation to match such standards.
- The use of baselines preferred by one (non-state) party as against other parties in a multi-stakeholder international IP system where a balance of interests is key, presents a methodological bias that implicates all parties other than the one choosing the baseline.
- The index fails to understand the analytical import of patent based incentive structures in choosing certain indicators.