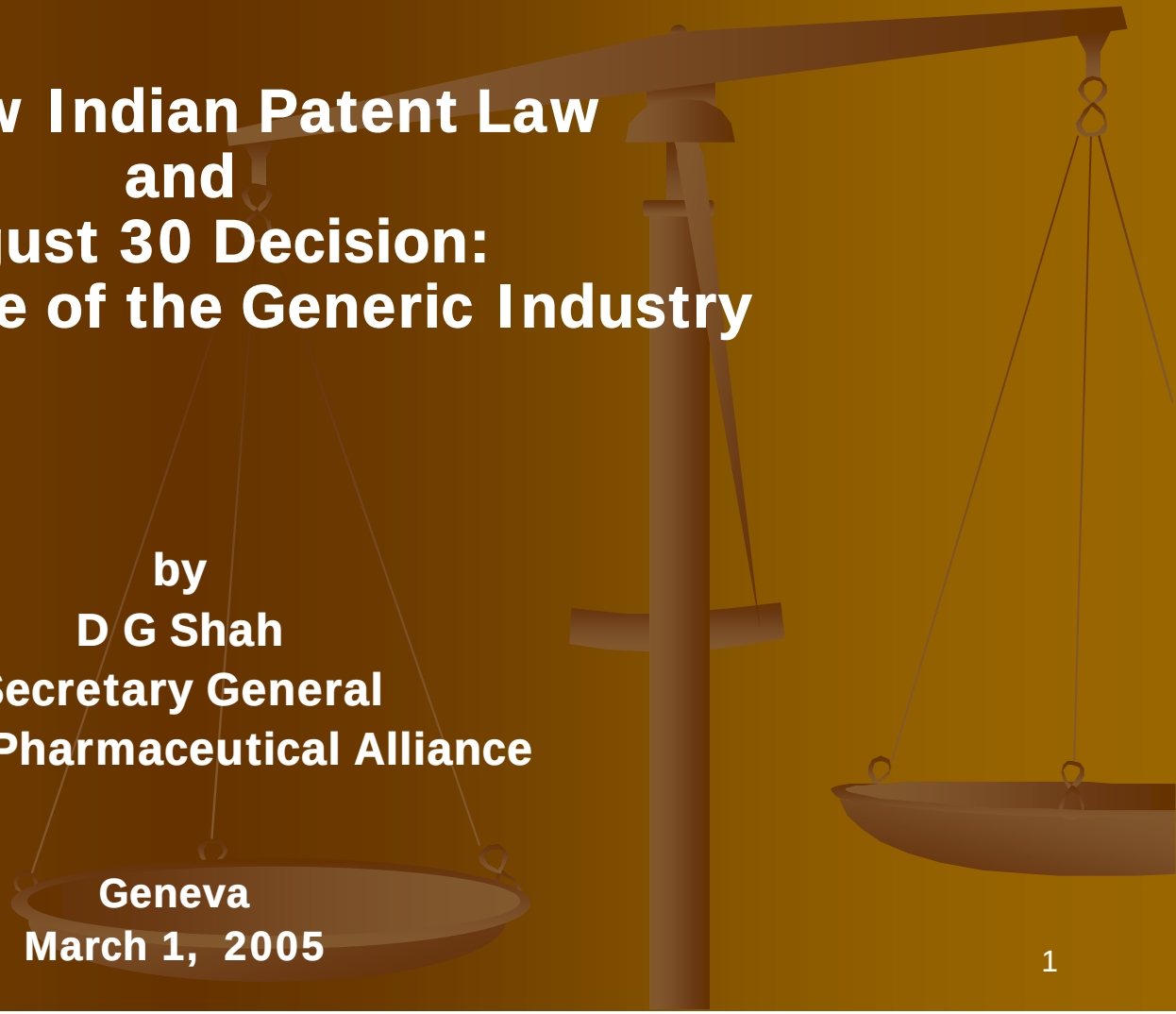
WHO-CIPIH
Commission on Intellectual Property Rights, Innovation and Public Health

The New Indian Patent Law and August 30 Decision: The Response of the Generic Industry



by
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Outline of Presentation

Indian Patent Law: Critical Provisions

- **Sec 3 : What are Not Inventions**
- **Sec 11A : Publication of Applications**
- **Sec 25 : Opposition to Grant of Patent**
- **Sec 39 : Prohibition to Apply for Patents Outside India**
- **Sec 92A : Compulsory License for Export**
- **Sec 159 : Power of Central Government to Make Rules**

Section 3: What are Not Inventions

The following are not inventions within the meaning of this Act:

d. **the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;**

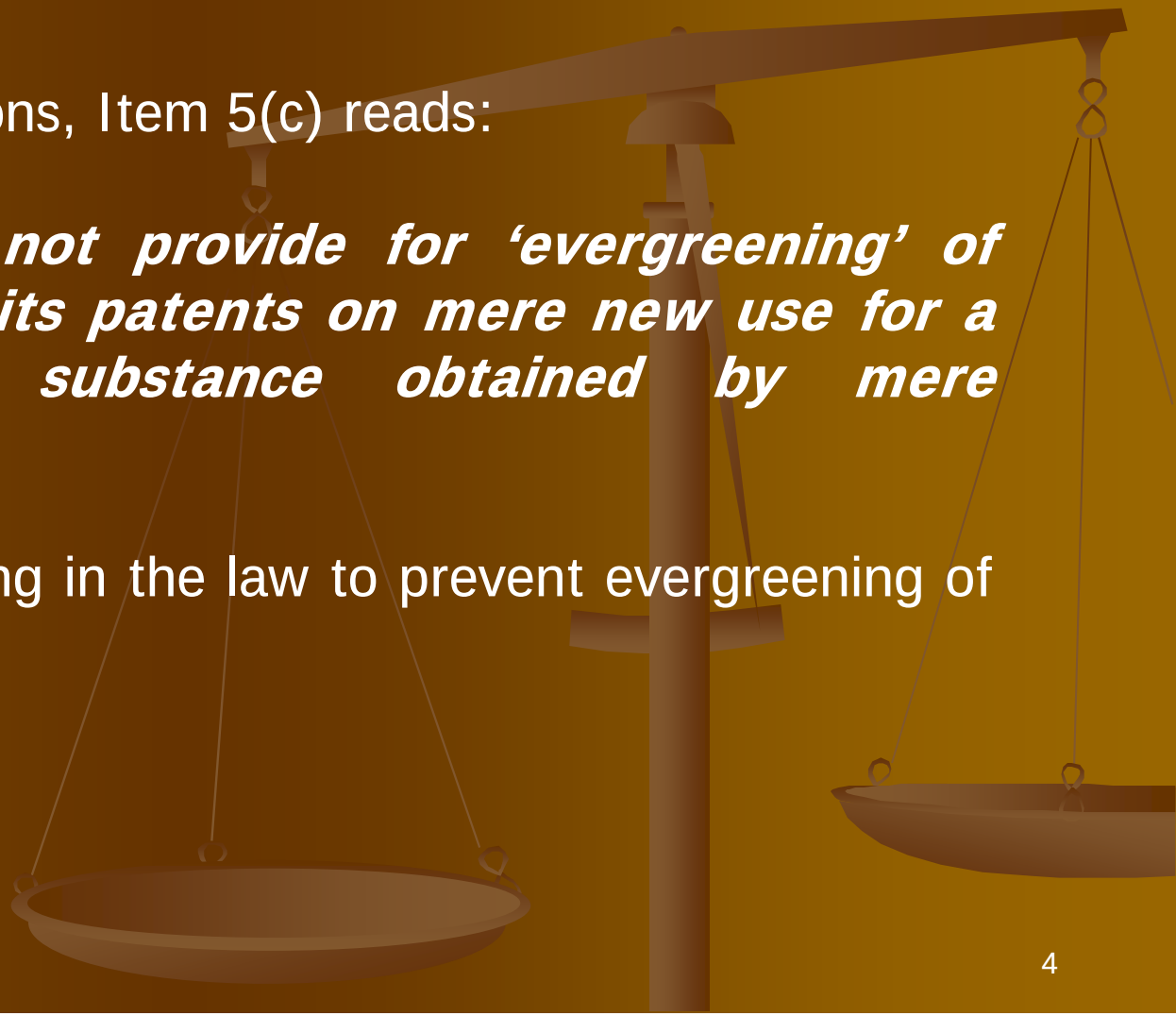
e. **a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;**

Government Intention

GoM Record of Discussions, Item 5(c) reads:

"Existing law does not provide for 'evergreening' of patents, as it prohibits patents on mere new use for a known substance, substance obtained by mere admixture, etc."

However, there is nothing in the law to prevent evergreening of other types.



Impact of Patenting Trivial Changes

Example-1: "Substantially Pure" (Fexofenadine Hydrochloride)

- **Patent (US 4,254,129) was granted to Aventis in 1979.**
- **Aventis obtained second patent (US 5,578,610) in 1996 claiming "substantially pure compound", which was indeed the product on the market, extending its patent life to 2016.**
- **This is a case where first the patent is obtained for the compound without any reference to purity. Thereafter, a patent is sought for a "substantially pure" compound. The second patent becomes a hurdle for generic products, as they are also "substantially pure".**
- ***If the legislation were to permit patenting of trivial changes (substantially pure), fexofenadine hydrochloride would become eligible for product patent as a post-1995 molecule.***
- **Total Sales of Product in India: Rs 300 mn.**

Impact of Patenting Trivial Changes

Example-2: "Particle Size" (Oxcarbazepine)

- Patent (US 3,642,775) was granted to Novartis in 1970.
- Novartis obtained second patent (US 20,030,190,361) in 2003 claiming "particle size" of certain specifications.
- This is a case where first the patent is obtained for the compound without any reference to particle size. Thereafter, a patent is sought for a "particle size" compound. The second patent becomes a hurdle for generic products.
- ***If the legislation were to permit patenting of trivial changes (particle size), oxcarbazepine would become eligible for product patent as a post-1995 molecule.***
- Total Sales of Product in India: Rs 160 mn.

Patenting Strategies that Delay Access

Example-1: Imatinib Mesylate (Novartis)

- The first patent application for imatinib and its salts including the mesylate salt, CH 1083/92 was filed in Switzerland in 1992.
- The patent application came in to public domain in 1993 on the publication of European equivalent EP-A-O 564409.
- Subsequently, a specific patent application CH 1764/97 for the beta crystalline form (polymorph) was filed in 1997 in Switzerland, extending the patent life of the drug by five years.
- Then, Australian equivalent AU 740713 on the beta crystalline form was filed in 1998.
- The Indian EMR is based on post-1995 application for a polymorph of imitanib mesylate.
- ***If trivial changes (polymorph) were not patentable,*** **imatinib mesylate** ***would not have been eligible for EMR.***

Patenting Strategies that Delay Access

Example-2: Rosiglitazone (GSK)

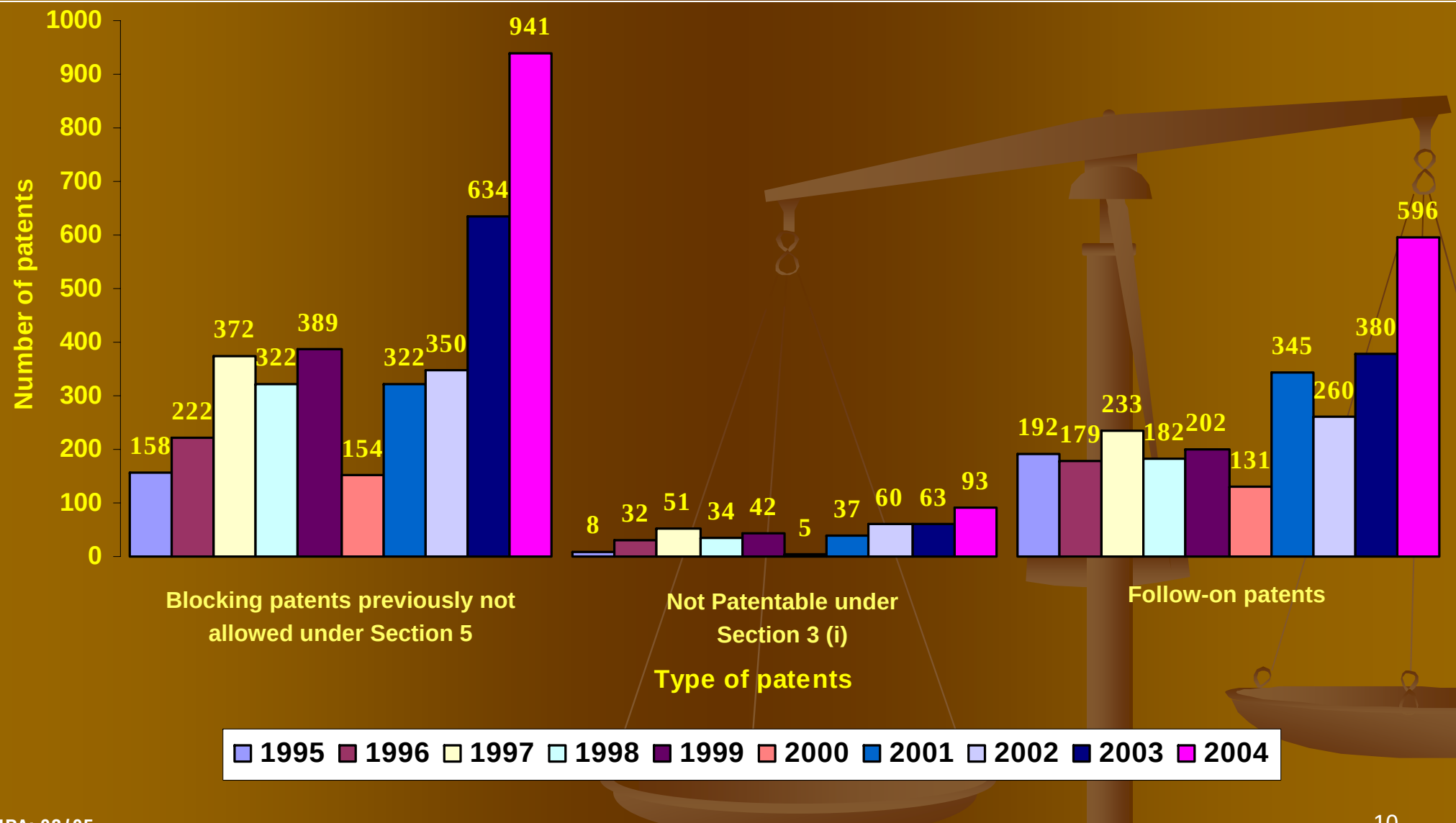
- The first patent for the product was filed in 1987 in the USA.
- Subsequently, a specific patent for “rosiglitazone maleate” was filed in 1992, also in the USA, extending the patent life of the drug by five years.
- The patent came in to public domain in 1994 on the publication of the international application.
- An equivalent patent was filed in Brazil in 1997.
- GSK claim for EMR in India is based on its post-1995 application.
- ***If trivial changes (hydrate) were not patentable, rosiglitazone maleate would not be eligible for EMR.***

Analysis of Pharmaceutical Patents Filed by MNCs in Mail Box

Year	Blocking Patents Previously Not Allowed Under Section 5			Not Patentable Under Section 3 (i)	Follow-On Patents			
	Product	Combination	Total	Method of Use	Composition	Process	Crystal Form	Total
1995	156	2	158	8	78	112	2	192
1996	217	5	222	32	101	74	4	179
1997	363	9	372	51	114	109	10	233
1998	309	13	322	34	74	101	7	182
1999	373	16	389	42	82	101	19	202
2000	147	7	154	5	47	72	12	131
2001	311	11	322	37	132	187	26	345
2002	314	36	350	60	120	124	16	260
2003	600	34	634	63	163	177	40	380
2004	856	85	941	93	287	239	70	596
Total	3646	218	3864	425	1198	1296	206	2700

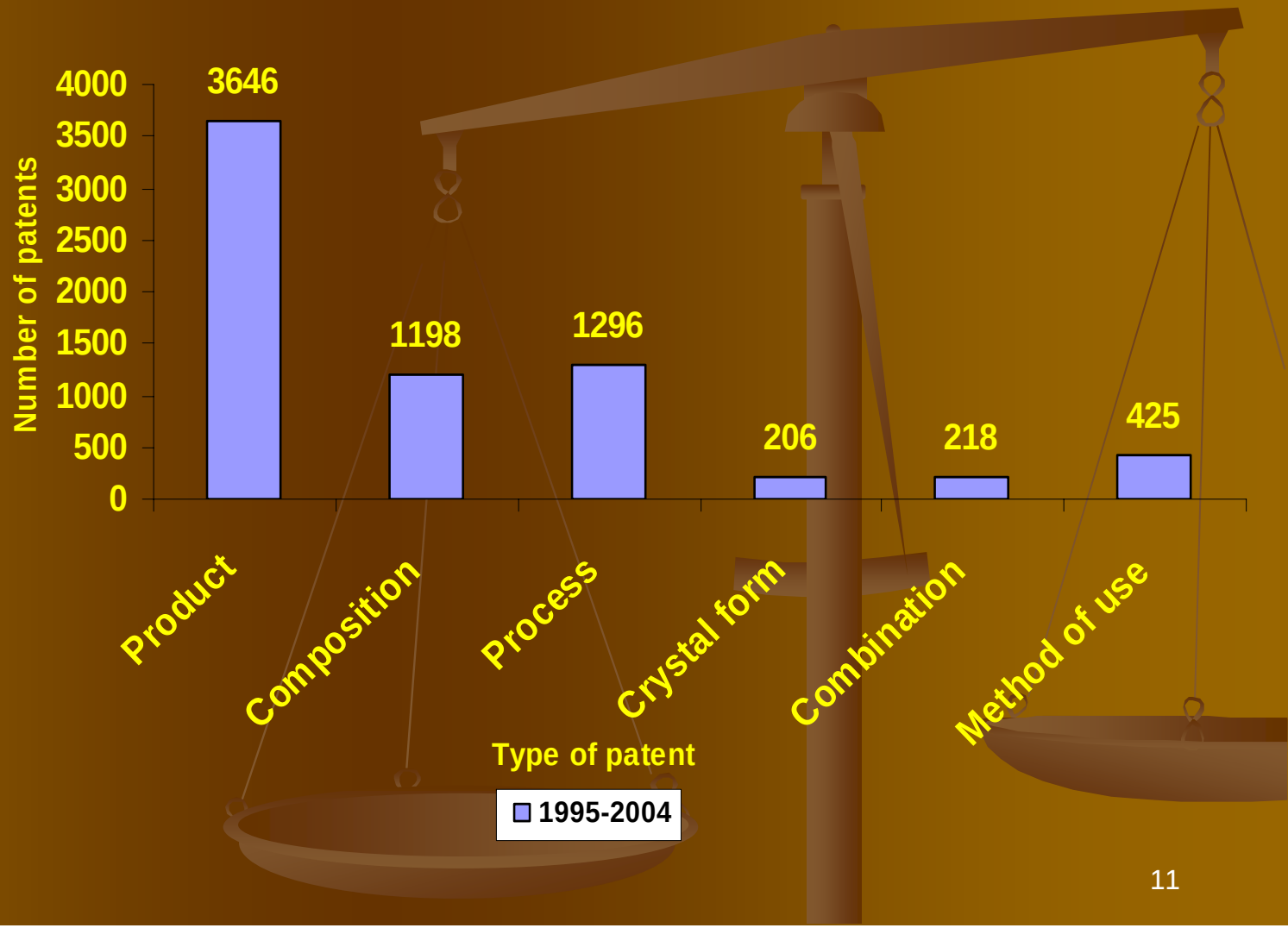
TOTAL FILINGS BY MNCs: 6,989

Trend Analysis (Patents Filings by MNCs at Indian PTO)



Number of Patent Filings by MNCs-1995-2004

Year	1995-2004
Product	3646
Composition	1198
Process	1296
Crystal form	206
Combination	218
Method of use	425
Total	6989

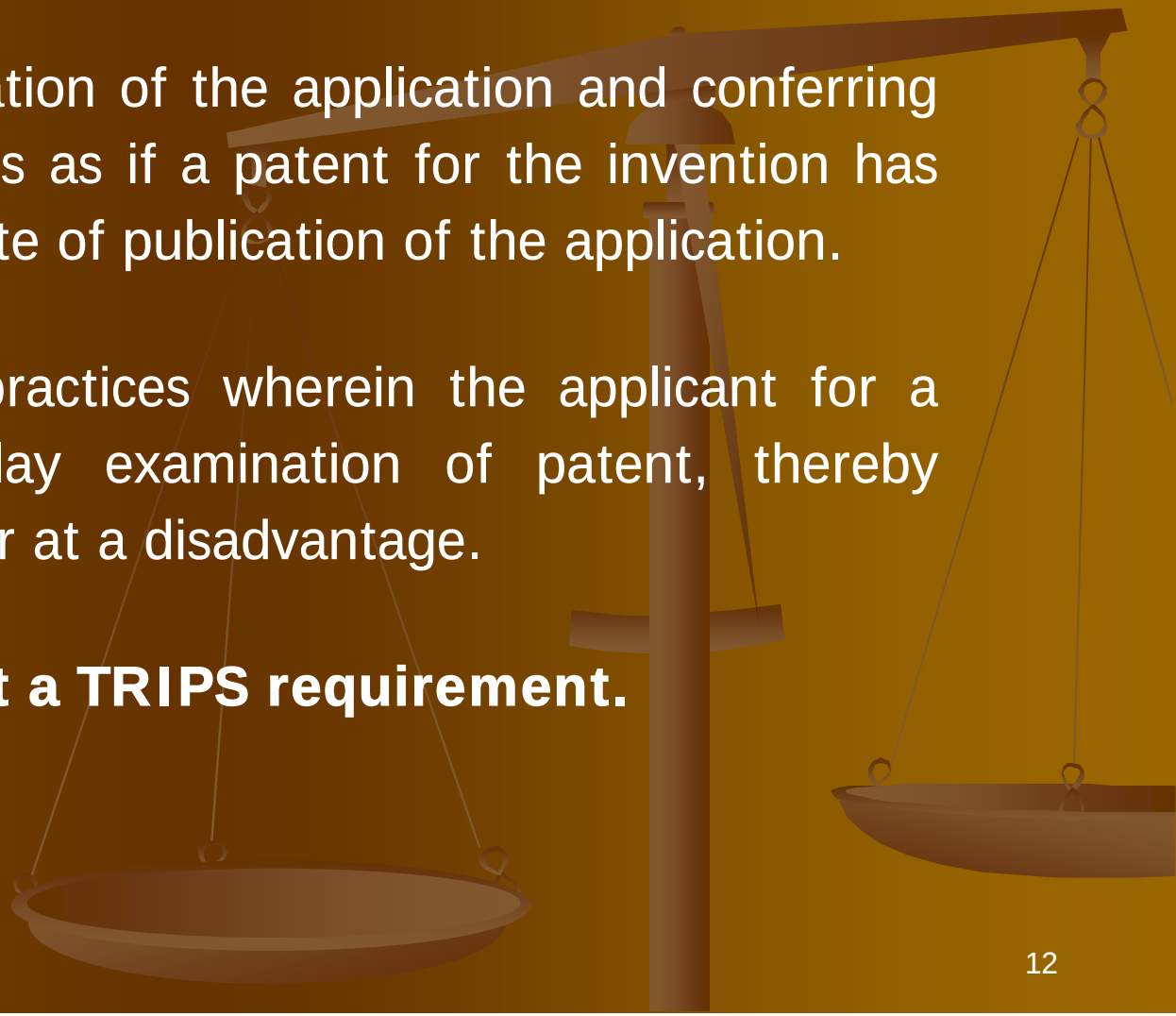


Section 11A: Publication of Applications

Option for early publication of the application and conferring like privileges and rights as if a patent for the invention has been granted on the date of publication of the application.

Potential for abusive practices wherein the applicant for a weak patent may delay examination of patent, thereby placing generic producer at a disadvantage.

This is not a TRIPS requirement.



Publication & Access to Patent Applications

- **The Patent Office posted a Special Notice on its website on 21-01-05 that all Patent Applications filed upto 20-07-03 shall be *deemed* to have been published.**
- **The Special Notice will apply to over 5,000 applications from the foreign companies. These include several applications for polymorphs and compositions covering pre-1995 molecules in the market.**
- **Not only the publication is "deemed", even the inspection fees and charges for photocopies of the documents have been raised steeply making patent information inaccessible.**
- **Recognizing the uncertainty and lack of information as to what exactly will happen and which drugs will be affected, there is a line of action that India as a developing country can take in order to mitigate the anticipated problems of lack of access to generic medicines. And, that is to make patent information easily accessibly both in print form and via on-line searchable database.**

Section 25: Opposition to Grant of Patent

Weakening of provisions for pre-grant opposition.

Canada and UK, which give priority to public interest, have tougher pre-grant-opposition provisions.

Pre-grant opposition is an important tool to forestall the granting of trivial and ‘frivolous’ patents without litigation, which is time consuming, expensive and beyond the means of local companies and organizations.

The Weakening is not a TRIPS Requirement

Section 39: Prohibition to Apply for Patents Outside India

The existing provision was for inventions relevant for defense and atomic energy only. This is now being expanded to cover any application outside India. This will be prejudicial to the interest of domestic pharmaceutical companies.

This is not a TRIPS Requirement

Section 92A: Compulsory License for Export

Fails to utilize TRIPS provisions re patent holder's permission and right to determine public-health emergency.

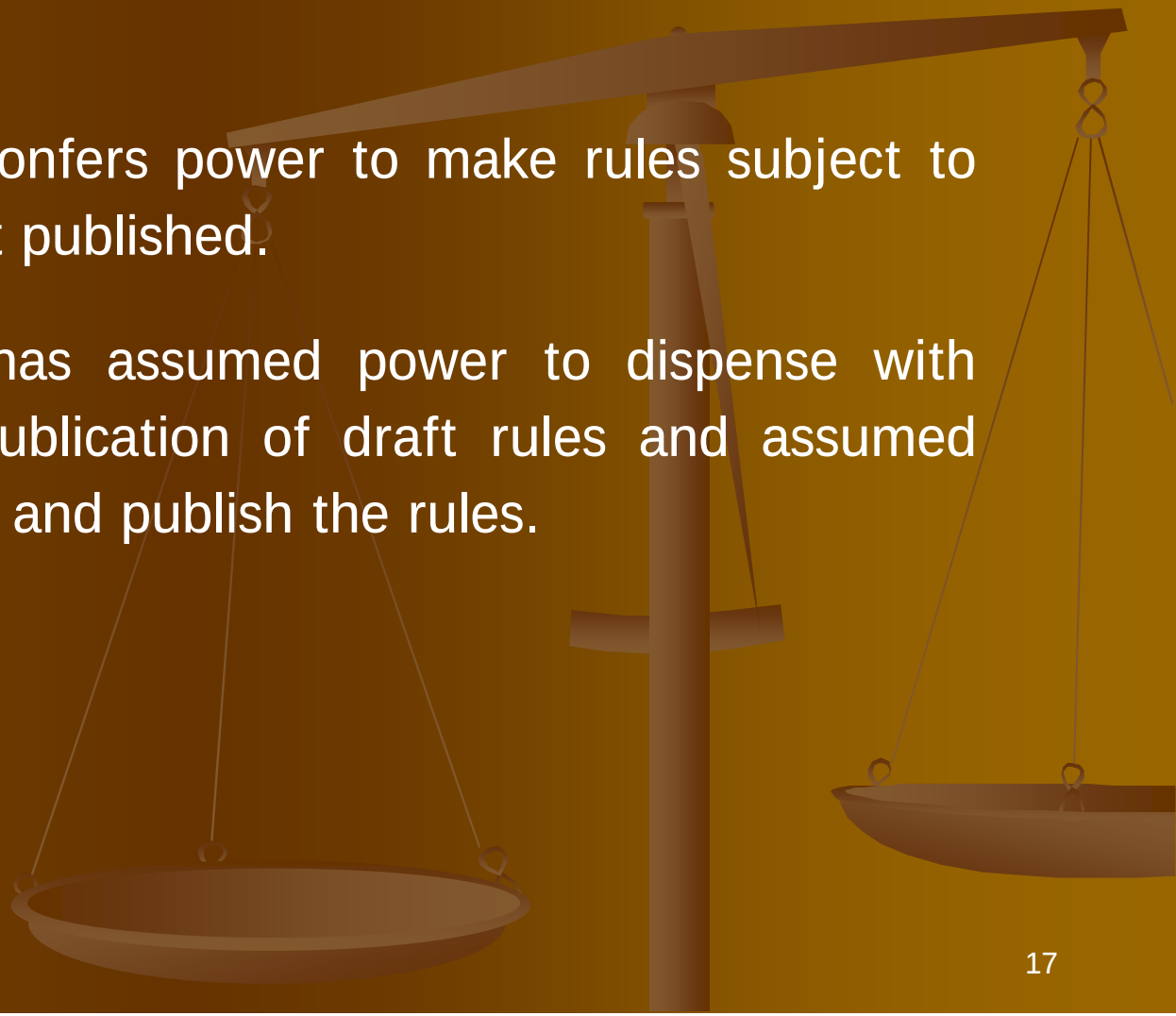
Controller of Patents obliged to make certain inquiries before taking any action.

Effectively gives the patent holder right to object to the compulsory license even before it is issued.

Even LDCs under the extended transition period are required to grant the Compulsory Licence.

This is TRIPs Plus

Section 159: Power of Central Government to Make Rules



The existing provision confers power to make rules subject to the draft rules being first published.

Now the Government has assumed power to dispense with condition of previous publication of draft rules and assumed absolute power to frame and publish the rules.

THANK YOU

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