

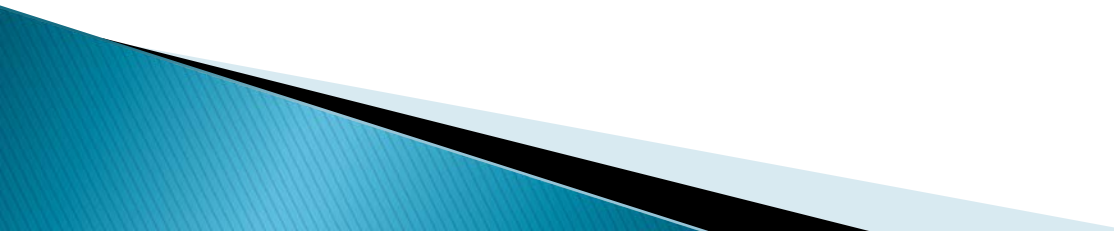
PPMA 5th Pakistan Pharma Summit

Patent Law and Access to Medicines

Issues, Challenges & Solutions

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Access to Medicines

- ▶ Health Policy Context
 - ▶ Medicines and Essential Medicines
 - ▶ Access, Availability and Affordability
 - ▶ Access to safe, effective and quality medicines for all is one of the targets of the Sustainable Development Goals
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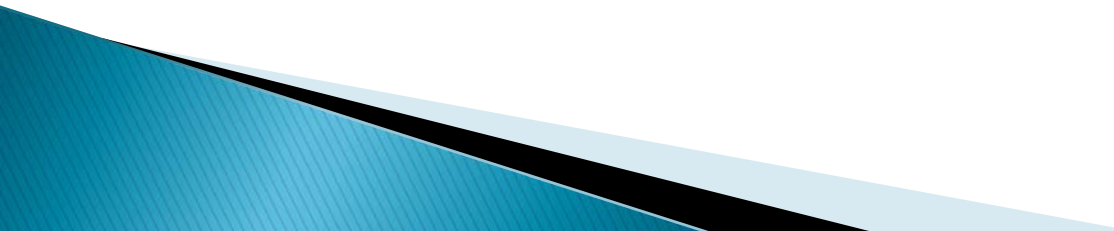
WHO Roadmap

▶ Roadmap on access to medicines and vaccines 2019–2023

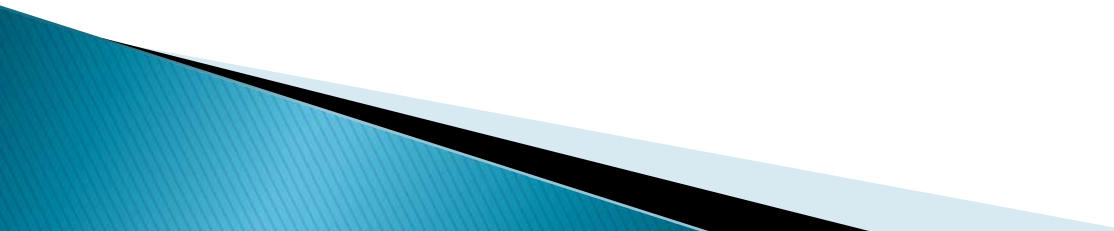
- Research and development for medicines and vaccines that meets public health needs
- Fair pricing and financing policies
- Application and management of **intellectual property** to contribute to innovation and promote public health
- Procurement and supply chain management
- Appropriate prescribing, dispensing and use
- Regulatory systems that ensure quality, safety and efficacy of medicines and vaccines
- Preparedness for emergencies
- Good governance
- Collecting, monitoring and using key data

Health workforce capacity for access to medicines and vaccines

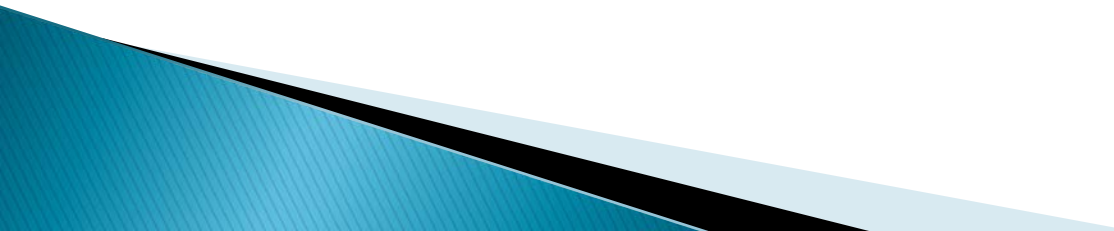
Patent Law and Medicines

- ▶ Industrial Revolution
 - ▶ Post-Industrial Revolution and Knowledge Economy
 - ▶ Patents
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Game of Patenting!

- ▶ Processes & Products
 - ▶ Follow on Patents
 - ▶ Secondary patents
 - ▶ Diagnostics
 - ▶ Life forms
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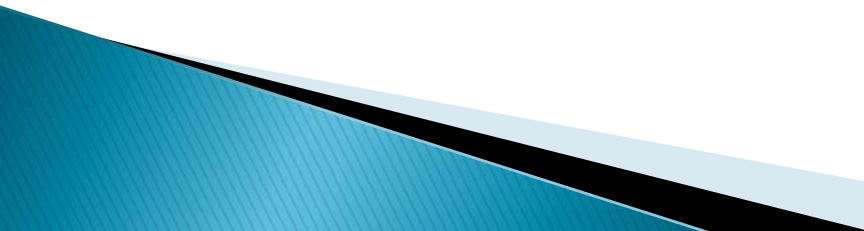
Problem of Patents: Tragedy of Anti-Commons

- ▶ From Tragedy of Commons to Tragedy of Anti-Commons
 - ▶ Lessons from Business Method Patents
 - ▶ Lessons from Biotech Patents
 - ▶ Lessons from Telecommunication Patents
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Issues: Patent Linkage I

- ▶ Patent linkage refers to practice of linking drug marketing approval to the status of the patent of the originator's product and not allowing the grant of marketing approval to any third party prior to the expiration of the patent term.
- ▶ Whether the grant of drug marketing approval by the DRA, *ipso facto*, amount to a patent infringement?
- ▶ Whether the DRA should act as a 'patent police' to enforce private rights of individuals?

Issues: Patent Linkage II

- ▶ Whether the DRA has the statutory powers and institutional capacity of dealing with complex issues of patent scope, validity and infringement?
 - ▶ Whether the practice of patent linkage potentially undermines the “Bolar/Early Working” exception that encourages quick access to the post patent markets for generic medicines?
 - ▶ Whether the remedy to challenge a patent by way of counterclaim can be closed off, by preventing a party other than the patentee from selling a patented product, before the other party has actually infringed the patent?
 - ▶ Whether existence of a system of patent linkage can be assumed without any specific statutory or other legal provision enabling such linkage?
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Issues: Patent Linkage III

Examples of Linagliptin

Applicant	Product	Year	Status
High-Q Pharma, Karachi	Letrum	2015	Pending
Schazoo Pharma, Sheikhpura	Lina-K	2017	Pending
Getz Pharma, Karachi	Linapta	2018	Pending
Searle Company, Karachi	Dialin	2018	Pending
CCL Pharma, Lahore	Ccldiolin	2015	Pending
Medisure Labs, Karachi	Medjenta	2015	Pending
Genix Pharma, Karachi	Empalin	2012	Pending
Martin Dow, Karachi		2011	Pending

Issues: Patent Linkage III

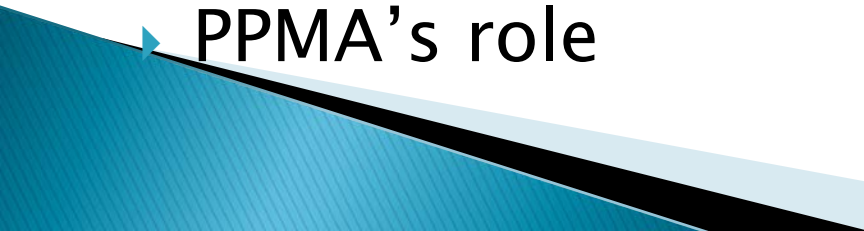
Examples of Ferric carboxymaltose

Applicant	Product	Year	Status
Shaigan Pharma, Rawalpindi	Oxyplex	2016	Pending
Getz Pharma, Karachi	Iroinject	2013	Pending
Genix Pharma, Karachi	FCM	2013	Pending
Akson Pharma, AJK	Ironjet	2013	Pending
S.J. & G. Fazul Ellahie, Karachi	Carefer `	2014	Pending
Tabros Pharma, Karachi	Ferry-FC	2015	Pending
Sami Pharma, Karachi	FE-Malt	2015	Pending
Global Pharma, Islamabad	Gloject	2015	Pending

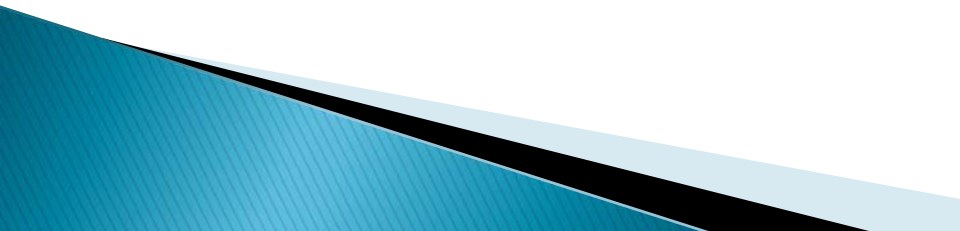
Issues: Patent Law Reforms

- ▶ Regulatory Capture
 - ▶ US Commercial Law Development Program and IP Law up-gradation
 - ▶ Trainings of Patent Office Officials
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Issues: Abolishing Pre-Grant Opposition

- ▶ Importance of Pre-Grant Opposition
 - ▶ The Art of Pre-Grant Opposition
 - ▶ Patent Opposition Databases and Networks
 - ▶ Under Utilization of System doesn't Mean that it is Ineffective!
 - ▶ PPMA's role
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Solutions: Role of PPMA

- ▶ Proactive Role of PPMA is needed
 - ▶ Future of your Product Cycles
 - ▶ Challenges of Licensing and Changing World of Patent Licensing
 - ▶ Investment in Human Resource and Research
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Thanks

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