

# COMPULSORY LICENCE

in Germany

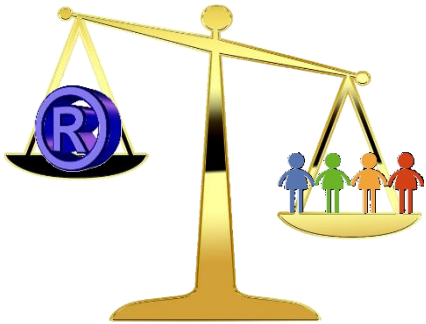




## 1877 - GERMAN PATENT ACT



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Public interest



Dependent patent



Plant breeders' privilege\*



Export to developing countries\*\*



FRAND licence

\*directive 98/44/EG

\*\*regulation EC No 816/2006; § 85a PatG



## RELEVANCE OF PUBLIC INTEREST CL

|              |   |
|--------------|---|
| 1877 to 1911 | Compulsory licences (CL) were granted regularly   |
| 1911 to 1949 | rarely  |
| 1950 to 2016 | only one CL granted by Federal Patent Court, but revoked by Federal Supreme Court in 1995 |



# LEGAL FRAMEWORK

## *Paris Convention\* Article 5 A*

[..]

- (2) Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

\*Stockholm Act 1967, introduced with the Hague Act 1925



# LEGAL FRAMEWORK

## *TRIPS Article 31*

### *Other Use Without Authorization of the Right Holder*

Where the law of a Member allows for other use\* of the subject matter of a patent without the authorization of the right holder [...] the following provisions shall be respected:

[..]

- (b) such use may only be permitted if, prior to such use,
  - the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions
  - and that such efforts have not been successful within a reasonable period of time. [...]
- (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, [...]

\*other than that of Article 30 TRIPS „Exceptions to rights conferred“



## LEGAL FRAMEWORK

### *TRIPS Article 31, continued*

#### *Other Use Without Authorization of the Right Holder*

- (d) such use shall be non-exclusive;
- (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
- (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
- [..]
- (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;



## GERMAN NATIONAL LAW

- German patent act provides for CL in the public interest\*
- and for CL for the owners of dependent patents\*\*
- CL can be granted by preliminary injunction, if accelerated grant of the licence is in the public interest\*\*\*
- The German Federal Patent Court (BPatG) decides about requests for CL
- Appeal may be filed at the Federal Supreme Court (BGH)

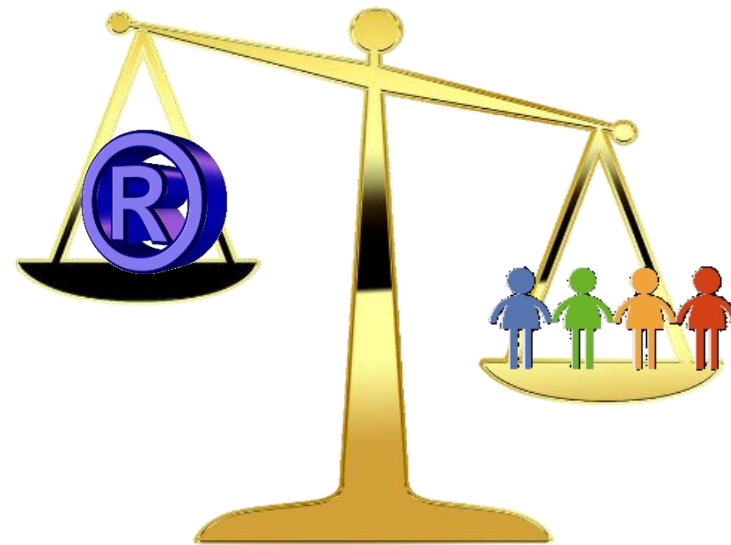
\* § 24 I PatG    \*\* § 24 II PatG    \*\*\* § 85 PatG





## PUBLIC INTEREST CL

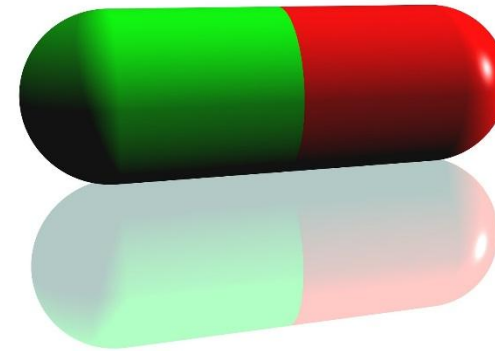
- Public interest must dictate grant of the licence, i.e. no milder means would be sufficient
- Public interest is not limited to public health!
- Environmental protection, safety measures, energy supply
- Availability of groundbreaking technology (e.g. CRISPR/CAS)
- Sufficient supply of the German market with a protected product





## PUBLIC HEALTH

- Small group of patients relevant enough\*
- Particularly, if group would be endangered should a drug no longer be available\*
- the more severe a disease, the more relevant are small improvements in therapy



\*BGH, Urt. v. 11.7.2017 – X ZB 2/17 (BPatG)



## DEPENDENT PATENTS

- Introduced with implementation of 98/44/EG
- Requirement of public interest replaced by
  - A. important technical improvement
  - B. of significant economic relevance
- Meant to facilitate CL for biotechnological inventions, but not limited thereto
- Licensee must grant cross-license





## EFFORTS TO OBTAIN AUTHORISATION

- Licensee must have sought after a license from Proprietor
  - A. under reasonable terms and conditions,
  - B. during an appropriate period of time.
- Attempt to obtain licence sufficient, even after filing request for grant of CL
- The licensee need not offer specified amount, it is sufficient to express willingness to pay adequate amount



## PROCEDURE

- Request for CL must be filed with Federal Patent Court with the Proprietor (not an exclusive licensee) as the Defendant
- Procedural rules of revocation proceedings apply
- CL are granted for EP and German patents, utility models, and SPCs
- Infringement of patent will not be examined in CL proceedings
- Licensee may file actions for declaration of non-infringement
- First instance decision may grant preliminary enforcement of CL, if requested and in public interest
- In urgent cases, CL can be granted by injunction



## AFTER CL GRANT...

- The patent can only be transferred together with the licence
- CL may only be transferred together with the whole entity, or the relevant part
- Licensee may request revocation of the patent with the competent authority, i.e. EPO, GPTO or Federal Patent Court.
- CL is valid only for Germany, exhaustion does not apply
- Licence fee may be changed under new circumstances, e.g. proprietor gives further licences, proprietor does not enforce patent against infringers



## REVOCATION OF CL

- CL may be revoked if
  - The reasons for its grant no longer exist, and
  - It is unlikely that the reasons will occur again
- Legitimate interests of licensee must be taken into consideration, e.g. licensee must be able to recover his investments
- CL will lapse together with the patent



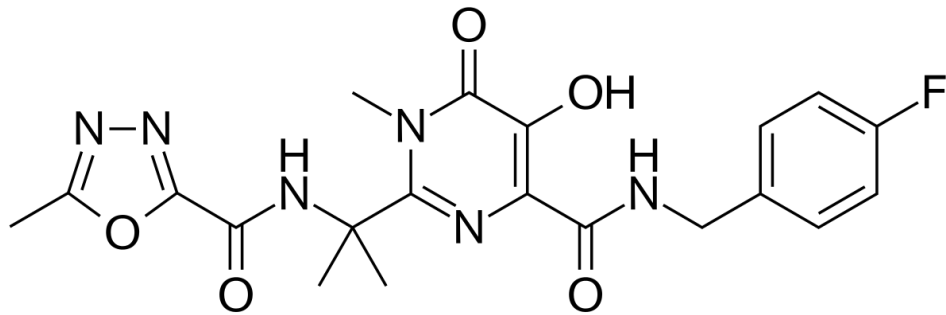
## RELEVANCE?

- No public interest CL granted in the Federal Republic of Germany for almost 70 years
- Similar in most developed countries
- There are provisions for compulsory licences in the public interest in all EU countries
- Mere presence of the law might encourage proprietors to give licences



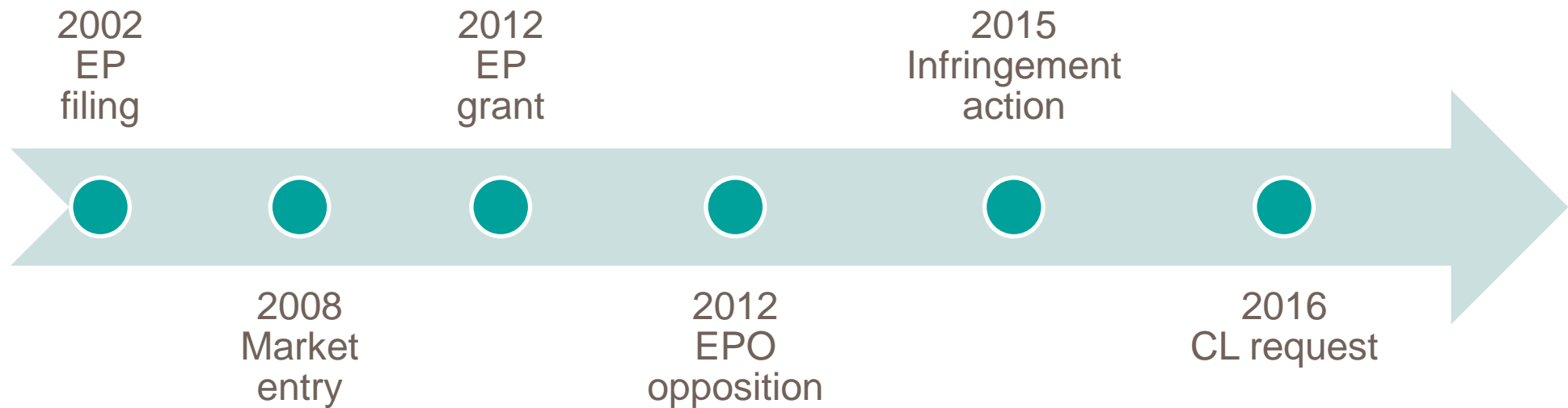


# RALTEGRAVIR





# SHIONOGI



# MERCK

EP 1 422 218



## HOW MUCH IS ENOUGH?

- In 2014 Proprietor approached licensee concerning infringement of a JP counterpart
- Proprietor offered licensing negotiations
- Proprietor made two offers for license fees (5 to 12.5 % of revenue)
- Licensee offered a lump sum compensation of 10 Mio. USD
- Proprietor argued that lump sum was not a real offer because of the low amount





## COURT PROCEEDINGS

- Licensee expressed willingness to pay reasonable fee, even if higher than the offered lump sum
- Licensee did not insist on upper limit
- Proprietor still considered 5 to 12.5 % of the revenue a reasonable license fee
- Court was satisfied that the lump sum offer was enough to comply with the „reasonable conditions“ requirement



## PUBLIC INTEREST

- Proprietor's patent right constitutionally protected
- Fact that Proprietor has a monopoly is not an abuse
- CL is last resort, if no other means can satisfy public interest
- For pharmaceuticals: no CL, if equivalent alternatives available\*



\* BGH, GRUR 1996, 190 - Polyferon



## NO EQUIVALENT ALTERNATIVE

- HIV infection is a very serious condition
- No other product with raltegravir available
- Two other integrase inhibitors were available\*
- HIV therapy is individual therapy
- There are patients for whom there is no equivalent alternative
- Fighting infectious diseases is always in the public interest
- Effective HIV treatment reduces risk of new infections



\*one of them sold by a partner of the Proprietor



## RESULT

- CL was granted by injunction
- Preliminary injunction necessary because district court set hearing date
- CL restricted to the dosage forms already sold
- Not restricted to patient groups
- Reasonable compensation to be determined in main proceedings



## LATER...

- District court in Düsseldorf stayed proceedings until EPO opposition decision
- Federal Supreme Court confirmed Patent Court's decision in July 2017\*
- EPO Board of Appeal revoked patent in October 2017 (Art. 123(2) EPC) \*\*
- Federal Patent Court decided in November 2017 that licensee had to pay license fee of 4% on revenue\*\*\*
- Fee to be paid for the interval from grant of CL to revocation of patent
- Revocation does not eliminate obligation to pay the fee

\*BGH, GRUR 2017, 1017 - Raltegravir

\*\*T 1150/15 – not published yet

\*\*\*BPatG, 3 Li 1/16 (EP)





## IMPACT?

- Awareness of CL might influence negotiations
  - with competitors
  - with health insurance organisations
- availability of many substances can be considered in the public interest
  - increased stratification / personalized medicine
  - more data available for small groups of patients
- „target-focused“ claim language used in patents



## COMPULSORY LICENCES UNDER THE UPC

- UPC has no competence to grant CL
- CL to unitary patents may be granted by the member states\*
- This has been criticized: MPI, „The Unitary Patent Package: Twelve Reasons for Concern”, Nr. 11
- The situation will be similar to the situation of conventional EP patents today (Art. 2 (2), 74 EPC)
- If an infringement action is brought before the UPC, defendant may seek CL for German territory at the Federal Patent Court.

\*EU regulation 1257/2012, recital (10)



## TRIFURCATION?

