

The Easy Cases

- Settlement goes beyond scope of the patent (geographic or material scope, duration) - e.g., Generic may not sell any products that compete with Originator's product (not just the product that infringes the patent)
- Evidence that patent obtained by fraud or objectively baseless

Licenses Without Payments

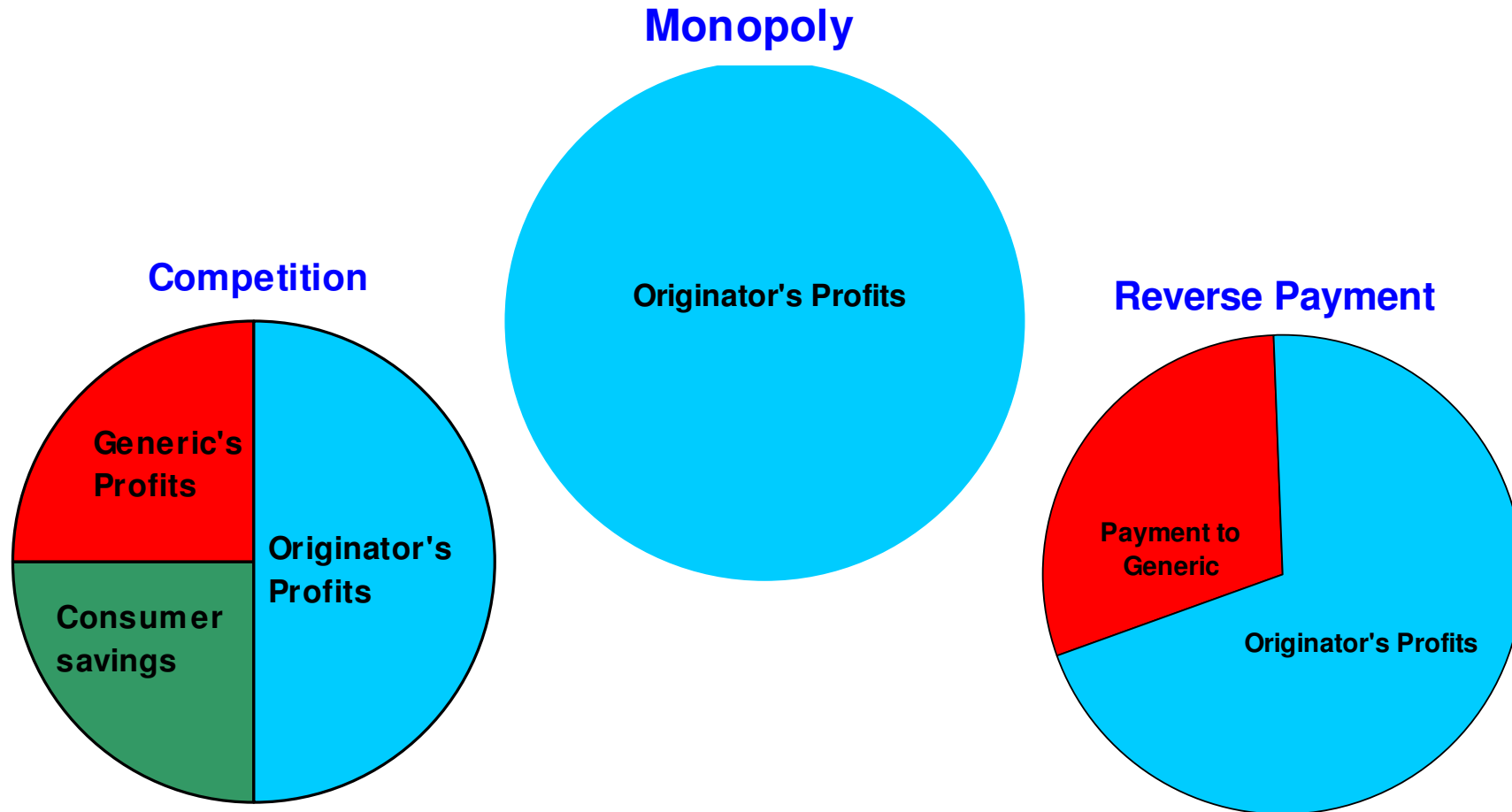
- License may limit generic entry because Generic cannot enter with its own product or it cannot set the conditions for the commercialization of its own product freely.
- License considered to be a value transfer.
- Exception: royalty-free license that allows immediate entry without further constraints concerning quantities, composition, pricing or other marketing conditions of the product
- Exception: Originator gives covenant not-to-sue as of a certain date, allowing Generic to enter early; no other constraints on Generic

Reverse-Payment Settlements Analysis

Commission's "counter-factual":

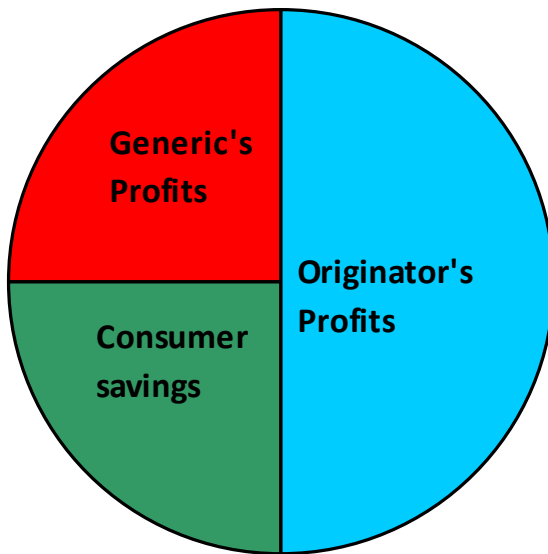
- In assessing the potential competitive effects of a reverse payment settlement, it is necessary to ask: What would be the situation absent the settlement? This is the "counter-factual."
- The Commission's counter-factual is that Generic would compete with Originator on the market, which would generate savings for consumers.

What Is Wrong With This Picture?



No Settlement: 2 Possible Outcomes

Generic Wins



Originator Wins



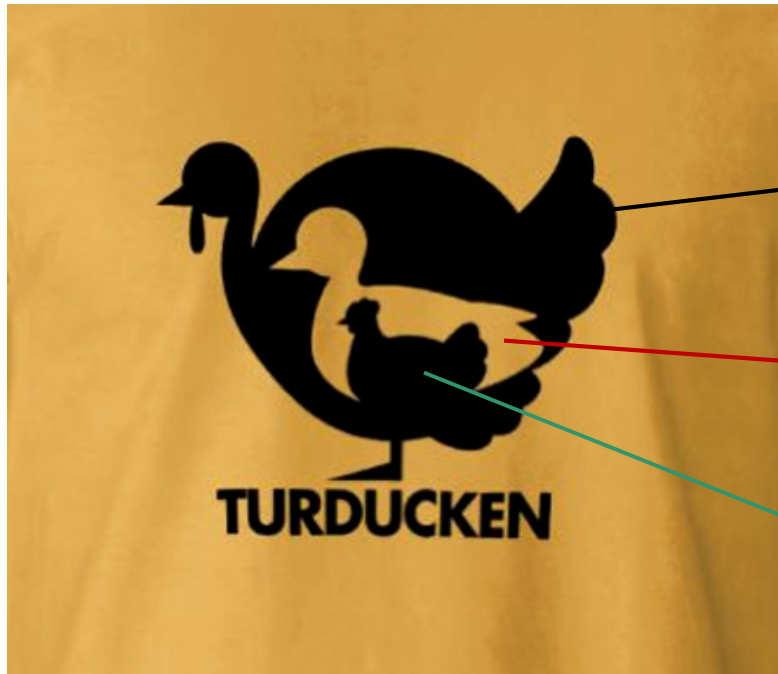
Reverse-Payment Settlements Analysis

Criticisms of Commission's counter-factual:

- It assumes that Generic is likely to win in litigation, which is an incorrect assumption.
- It treats the patent as consisting of only a probabilistic right to to exclude competition rather than a legal monopoly during the patent term.
- Highlights key element of the debate: What is the value of the patent? Is it just a probabilistic right? In granting patent, is patent office just saying that patent holder is more likely than not to have a patentable invention?

Reverse-Payment Settlements Analysis

- Commission ill-equipped to judge validity of patent -- would have to enter into an after-the-fact calculation of how likely a patent holder would be to succeed in the absence of a settlement
- “Predicting the future is precarious a best; retroactively predicting from a past perspective a future that never occurred is even more perilous. And it is too perilous an enterprise to serve as a basis for antitrust liability” *FTC v. Watson Pharmaceuticals, US Court of Appeals for the 11th Circuit (April 25, 2012), p. 34.*



Settlement of patent case

Competition law case about
settlement of patent case

Patent case

A Better Approach

- Assume that patent is valid and infringed unless compelling evidence to the contrary (i.e. patent is nothing more than a sham).
- Assumption that patent is valid is more consistent with patent system than an assumption that it is invalid.

Caution in Applying U.S. Approach to Europe

- No Hatch-Waxman in Europe, i.e. no exclusivity for first generic
- Legal tests are different: no perfect European equivalents of U.S. *per se* test or rule of reason test
- Possibly greater asymmetry of risk in Europe due to multiple jurisdictions
- But U.S. judgment may be useful to EU General Court as point of reference for a judicial compromise

Relevance of Reverse Payment

Is the direction of the payment relevant?

- Commission: reverse payment is anti-competitive because it suggests that Originator must think that it is likely to lose in litigation, so it must make a payment to keep Generic off the market
- But direction of payment is a red herring – it is a function of the parties' relative bargaining positions and does not necessarily reflect the strength of the parties' claims.

Relevance of Reverse Payment

Asymmetry of risk:

- Reverse payment by Originator to Generic simply reflects asymmetry of risk – even if Originator very likely to win, this asymmetry means that it may not want to take a chance of losing.



Relevance of Reverse Payment

Key factors creating asymmetry of risk:

- Originator may face mandatory price reductions in jurisdiction of the litigation.
- Originator may face cascading price reductions in other jurisdictions due to reference pricing.
- Originator may incur significant damages due to length of litigation that it may have difficulty recovering.