Gilead versus Generics in Ireland
Summary of case and observations from court

On October 3, 2017, Gilead Sciences went before the Commercial Court to seek injunctions against 3 generic manufacturers (Mylan, Teva, and Accord (Actavis)) to prevent them from marketing generic versions of Truvada in Ireland. The cases were heard by Mr. Justice McGovern in Court 1 of the Four Courts in Dublin. Hearings continued through the 4th and 5th of October. A judgment date has been scheduled for December 6, 2017.

Accord settled for damages in advance of this court date, but Mylan and Teva will continue to oppose the injunction. Gilead is represented by McCann Fitzgerald, Mylan is represented by Acuatus, TEVA by Mason Hayes & Curran.

The record numbers for the two currently active proceedings are 2017/5984 P (Mylan) and 2017/6494 P (Teva).

General background to the cases

Gilead Sciences manufactures Truvada, a single pill that combines two drugs (tenofovir disoproxil fumarate and emtricitabine) which are used primarily to treat HIV (although tenofovir is also used to treat hepatitis B). For HIV treatment, Truvada is combined with one or more other drugs to make an effective treatment combination. These same drugs are also used in several single pill regimens, which combine a complete multi-drug treatment regimen into a single, daily pill.

In addition to treating HIV, Truvada is also used by HIV-negative people as prophylaxis to prevent HIV. This use of Truvada is a safe and highly effective HIV-prevention method known as pre-exposure prophylaxis or PrEP. Truvada is licensed for use as PrEP in the European Union, although it is currently available through national health systems only in France, Belgium, and Scotland. Portugal has announced plans to make PrEP available, and it is also available in Norway, which is not an EU member.

Gilead's patent for Truvada expired in July of 2017. However, they had already obtained Supplementary Protection Certificates (SPC) which extend their exclusive right to market Truvada in many European countries (including Ireland) until 2020. The validity of those SPCs is being challenged in a number of countries, including England and Wales (now referred to the EU Court of Justice), France and Germany (this list is not necessarily exhaustive). Injunctions were not granted in France or Germany and generic versions of Truvada are already being marketed in France (and possibly Gemany). NHS Scotland also recently announced that they will be using generic versions of Truvada for both treatment and PrEP.

Irish proceedings

The following is a brief account of the details of the Irish cases and some highlights of what was discussed in court.

In the current actions, Gilead is seeking a temporary (or "interlocutory") injunction to prevent the marketing of generic versions of Truvada in Ireland until a suit contesting the validity of Gilead's Irish SPC can be heard. The feasible date for when the proceedings regarding the SPC could begin was a matter of disagreement, in large part because a

ruling from the EU Court of Justice on the English case (Teva UK, et al., v. Gilead Sciences)—which would be relevant for the Irish case—is not expected until some time in 2018.

The first filings are recorded on July 3, 2017 for the Mylan case and July 17, 2017 for the Teva case (Notice of Court Motion and Affidavits). Additional affidavits were filed in September and October by all parties.

Much of the discussion in these proceedings focused on the potential harm to Gilead or the defendants that would be caused by granting the injunction or not granting it, as well as questions about how or whether damages could be assessed to remedy any potential harm.

The first day in court was given to Gilead's barrister to make their case. The second day began with another hour for Gilead, followed by 3 hours for Mylan to present their arguments. The third day began with 3 hours for Teva to present, followed by a final hour for Gilead to respond to Mylan and Teva's arguments.

Affidavits from two independent doctors were referenced frequently during the proceedings. One, introduced by Mylan, is from Dr. James (Shay) Keating, a Dublin-based doctor with extensive experience in HIV treatment. The second, introduced by Teva, is from Dr. Fiona Lyons, who also has extensive experience with HIV care and treatment and who is currently employed by HSE as National Clinical Lead for the National Sexual Health Strategy.

Gilead argues that granting the injunction would maintain status quo (exclusive access, current pricing), while not granting injunction would introduce massive changes in market which would be difficult to undo or to compensate for.

There's discussion of term of injunction, and how soon main SPC challenge could go forward. Gilead suggests Q2 of 2018 realistic, seeks 9 month injunction. The defendants say they hope for speedy resolution, but worry that Gilead will seek to draw out litigation to extend period of injunction (if granted).

Gilead's primary claim is that they will suffer irreparable damages if they injunction is not granted. Specifically they pointed to direct losses of sales of Truvada if the HSE substitutes generics for branded Truvada, but they also emphasised potential losses from "splitting" of single pill regimens (SPRs) such as Atripla, as well as concerns about losing sales of TAF-based products. Gilead argues that these indirect harms (loss of sales of other products) are difficult or impossible to track because there are no available registers tracking individual patient prescriptions in Ireland (thus no way to know if patients are moved from a branded SPR to a combination of generics).

Both generic companies point out that SPC is for Truvada specifically, and argue that impact on other products (e.g. TAF and SPRs) not within scope of SPC, thus not liable for damages.

Affidavits from doctors indicate strong patient preferences for SPRs, which guides prescribing in Ireland, suggest doctors are not cost-conscious when prescribing. Keating calls SPRs "the gold standard" for treatment and is a strong patient preference. Would not convert from SPR to identical multi-pill regimen (nor from TAF to TD-based regimen). Disagreement over relevance of NHS policy documents which endorse generic substitution/splitting for cost savings.

According to Gilead, 1,200 patients (about 25% of all people in treatment in Ireland) currently take Truvada. They also claim that sales have declined recently, in part because patients are being switched to TAF-based products.

Generally, Gilead argues that the market is volatile, and this makes it difficult to assess harm or damages to compensate for harm. The generic manufacturers disagree, arguing that lost sales can be accounted for by tracking sales of generics. They also argue that pharmaceutical companies have sophisticated market tracking abilities, and that the market in question (for treatment) is relatively small (under 5,000 people) and limited (products dispensed through only 9 pharmacies).

Gilead suggests that generic versions would be priced 60% lower than Truvada (something reflected in other European markets where they've been introduced), but that competition will eventually drive the price even lower.

Gilead asks why defendants waited so long to challenge validity of SPC (originally issued 2009, came into effect in July, 2017 at expiry of Truvada patent). Defendants point to litigation in other jurisdictions and suggest that Gilead should have expected a challenge in Ireland as well.

There's much debate over how quickly generics might be available, the speed of uptake by HSE and within the 9 clinic-associated pharmacies which handle ARVs for HIV treatment in Ireland. Gilead suggests generic substitution can take place "within weeks." Generics suggest there is institutional inertia and process would be considerably slower due to number of bureaucratic layers involved in purchasing and distributing ARVs in Ireland.

Gilead argues that if injunction is not granted they will be forced to either keep prices high (in which case they will lose considerable market share) or to drop them to compete with generics (which will cause ripple effect in other European markets, and make it difficult to raise prices if they prevail on SPC challenge). Generics argue that in either case, if Gilead prevails on SPC challenge calculating damages (based on sales of generic products) will be completely straightforward.

Teva notes that they are poised to be first to enter market, that they will suffer irreparable harm if they lose "first mover" advantage.

PrEP

Gilead suggests that if the injunction is not granted and generics are introduced, their application to HSE for reimbursement for PrEP will be "fatally interfered with" and HSE will instead reimburse for much-cheaper generics. Generics argue that at Gilead's current price, HSE won't reimburse, so these aren't real losses (since it's a market they would not actually be able to enter). Teva even suggests that Gilead would be better off if PrEP approved with generics because if Gilead prevails on SPC, they'd be reimbursed for sales they might not otherwise have made.

Gilead suggests that negotiations with HSE on PrEP are progressing, that their application for reimbursement could be approved in relatively short time (reference to NCPE 90-day clock on/off time frame for full pharmacoeconomic review). Affidavit from Gilead's Laurence Wild suggests possible routes to reimbursement outside of NCPE process through commercial discussions or possible revised application for rapid review, which could accelerate process.

Mylan suggest that Gilead's suggestion that they would get PrEP approval in Ireland within next nine months (referring to proposed term of injunction) is speculative, citing example of NHS England which pursued trial (using Mylan generics) over buying Truvada for PrEP. Mylan cites Keating affidavit which expresses pessimism about how soon PrEP would be approved at current prices, suggesting 2-3 year time frame. Lyons affidavit notes that current price of Truvada raises concerns about affordability of PrEP within HSE.

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