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Select Competition Issues arising from changes in the Distribution of Pharmaceutical Products in South Africa

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1. Introduction

Significant changes have taken place in the distribution stage of the pharmaceutical supply chain in the South Africa during the past decade. These have led to a series of complaints and applications for interim relief to the competition authorities. The Competition Tribunal has delivered some judgements that have been in favour of the pharmaceutical manufacturers and others, in favour of the wholesalers.

The purpose of the paper is to reflect on the changes that have taken place in the distribution stage of the pharmaceutical supply chain, and to flag a selection of issues that arise in an assessment of the competition impact of these changes. As a case is currently in process at the Tribunal, it is important to skirt *sub judice* territory, and therefore this paper does not present a complete review of Tribunal decisions.

This paper starts with a brief review of recent developments in the pharmaceutical industry in South Africa. The changes within the distribution stage of the supply chain are particularly pertinent in the context of the series of competition cases that have been decided upon by the Competition Tribunal since 1993. We then flag select issues that are relevant to a consideration of the competition impact of the joint exclusive distribution ventures that have been established by groups of pharmaceutical manufacturers or the exclusive dealing arrangements that manufacturers have entered into with distribution enterprises. This exercise emphasises the complexity of such assessments, to which the ongoing rounds of cases before the Tribunal, are also testimony.

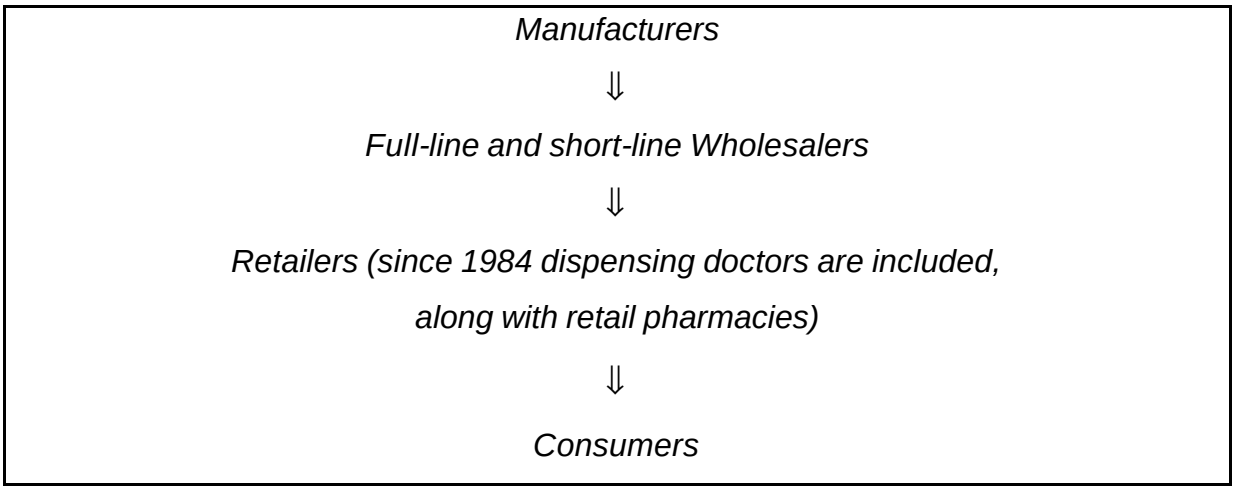
2. Developments in the South African Pharmaceutical Industry

Until 1993, the South African pharmaceutical supply chain[1] followed the traditional, and still predominant, international model.[2] This model is presented in Figure 1. Multinational pharmaceutical companies feature prominently in the production stage

[1] Focus in this paper is on the private segment of the total health care market, where delivery is in private hands.

of the supply chain. Distribution of pharmaceutical products is by independent wholesalers, who buy stock for their own account from manufacturers, and on-sell to retailers. Wholesale distribution of pharmaceutical products is done either by full-line or short-line wholesalers. Full-line wholesalers distribute the full range of available pharmaceutical products, and short-line wholesalers trade in a selection of products only.

Figure 1. Pharmaceutical supply chain pre-1993



Wholesalers cover their costs and make a profit based on the difference between the price at which they buy form the manufacturers and that at which they on-sell to the retail trade. The price differential takes the form of a discount (historically 17.5%) granted by manufacturers to wholesalers off the list price. Wholesalers pass on a significant portion of this discount, as is demonstrated by reported margins, to retailers as they compete for market share. Retailers on-sell to consumers in the final stage of the supply chain. These are pharmacies (mostly individually owned, although several retail chains do exist) and since 1984, dispensing doctors.

The pharmaceutical supply chain is usually described as a producer-driven one, despite the specific consumer demand characteristics, especially in the private segment of the health care market. This description reflects the significant market

[2] IMS Health: World Review and Pharmaceutical Distribution Data

presence and influence of the large multinational pharmaceutical producers in the health care market.

The international market for the production of pharmaceutical products has seen several waves of merger and acquisition activity in recent years, as these firms have tried to negotiate the myriad of changes, not only in pharmaceutical research and manufacture, but also in the regulatory environment and in the demand for pharmaceutical products. The South African pharmaceutical industry has reflected international trends, and we present a selection of these developments here.

Changes in the regulatory environment and in consumer demand

The private segment of the market for pharmaceutical products (this is the focus of this paper) is characterised by highly inelastic demand. This results from the 'must have ' nature of ethical or prescription drugs, which is supported by the power of the doctor's pen. The inelasticity is further enhanced by the extensive membership of medical aid schemes in this market segment. Since the cost of such drugs is veiled by the medical aid scheme, it does not directly confront the consumer, with the result that price sensitivity is muted.

This inelasticity may, however, be changing for a number of reasons, some of which relate to changes in the regulatory environment. The amended *Medicines and Related Substances Control Act*, No. 101 of 1965, proposes mandatory generic substitution. A pharmacist will be required to inform 'all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine' (Section 22F), and to dispense 'an interchangeable multi-source medicine instead of the medicine prescribed….unless expressly forbidden by the patient to do so' (*ibid*). This, along with the provisions to facilitate parallel imports (Section 15C (b)), is likely to increase the elasticity of demand for ethical or prescription drugs. Along with this, another significant challenge for producers is implicit in the proposed single exit pricing (Section 22G, 3(a)). This means that a single price will be prescribed for manufacturers when they sell to anyone other than the state. The differential

system of discounts operated by some manufacturers and wholesalers will no longer be permissible.

The *Medical Schemes Act*, No. 131 of 1998 (effective from 1 January 2000), sets out the conditions applicable to the admission of an individual to a medical aid scheme (Section 29 (n)). The terms and conditions applicable to the admission of a person as a member of a medical aid, and which provide for the determination of contributions on the basis of income or the number of dependants or both, does not take into account age, gender, past or present state of health of potential members, or the frequency of use of health services. The scope and level of minimum benefits may be proscribed, and adjustments to the scale and scope of benefits may be made within certain prescribed parameters.

At first glance, it would appear that the greater access to medical aid coverage would reduce the elasticity of demand. However after the first year of operation under the new Act, a number of Medical Aid Schemes announced changes to their benefit options – in particular the day-to-day coverage was reduced. This effectively means that the benefit ceiling is reduced, and the member is then responsible for costs of medical treatment and prescribed drugs incurred beyond that ceiling. This is likely to raise the elasticity of demand. The net effect of these changes, greater accessibility to medical aid coverage combined with less effective cover, is what matters.

It is however, even in view of these changes, on balance perhaps still true to say that the demand for ethical or prescription drugs is relatively inelastic – however it may well be that the elasticity is higher than it used to be as a result of the above changes. Manufacturers can be expected (rationally) to consider their market positions very carefully with respect to this set of changing conditions.

Changes in pharmaceutical distribution

Changes in the wholesale distribution of pharmaceutical products[3] have led to a series of applications for interim relief and complaints to the Competition Authorities since 1993. We catalogue very briefly here the changes that have taken place at this stage of the supply chain, with the establishment of three exclusive distribution enterprises.

International Healthcare Distributors

In 1992 a 'few like-minded pharmaceutical companies met to discuss the possibility of a distribution venture.'[4] 'Four companies, Boehringer Ingelheim, Roche, Bayer and Ciba-Geigy committed to the formation of a common distribution venture' (ibid). They submitted the proposal (that became International Healthcare Distributors (IHD)), to their principals in Europe and received formal approval in July 1993 from the European head offices. IHD started trading in December 1993. Since then a number of pharmaceutical manufacturers have joined IHD – it is now jointly-owned by eleven multinational manufacturers for whom it distributes pharmaceutical products to the retail trade.[5]

The entry of IHD, which we may describe as a joint, exclusive distribution venture, changed the configuration of the pharmaceutical supply chain, by effectively segmenting the market for the wholesale distribution of pharmaceutical products. The establishment of IHD involves a process of partial disintermediation, as traditional wholesalers are displaced with respect to the products of those manufacturers that distribute their products through IHD. Wholesalers, either, full-line of short-line may still buy the products of these manufacturers through their exclusive distribution agency, however they buy on exactly the same terms as the retailers to whom they on-sell. The discount structure which used to apply to

[3] The market for the wholesale distribution of pharmaceutical products has been defined, and accepted by the competition authorities, as the relevant market in a number of cases.
[4] www.ihd.com/milestone.htm - accessed 22/8/2001
[5] They are Abbott Laboratories, Aventis, Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, MSD, Novartis, Roche, Schering and Wyeth.

wholesalers (a 17.5% discount), has fallen away.[6] This, the wholesalers have argued (in submissions to the Competition Tribunal in support of Applications for Interim Relief) – makes their role (*ceteris paribus*)[7] as suppliers to the retail trade, commercially unviable. [8]

Kinesis Logistics

In 1998 a second joint exclusive distribution agency was established. Five pharmaceutical manufacturers[9] formed an investment company, Synergistic Alliance Investments (SAI) which acquired Druggists Distributors (DD) a traditional full-line wholesaler, to distribute the products of the principals and two other manufacturers. DD was converted from a traditional full-line wholesaler to a distribution agency to exclusively distribute to retail pharmacies, mail order (pharmacy) companies, dispensing doctors, private and public hospitals and clinics as well as (theoretically) wholesalers,[10] and trades under the style Kinesis Logistics.

Pharmaceutical Health Distributors

As of 25 November 2000, AstraZeneca (AZ) has used Pharmaceutical Health Distributors (PHD), another distribution firm, as its sole distribution agent – on a fee-for-service basis. In terms of the distribution agreement, the warehousing and distribution functions, as well as order generation, credit control and debt management are provided by PHD until the end of 2002. AZ maintains ownership of stock until sold to a third party.

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[6] It may be that there is a distinction between full-line and short-line wholesalers as regards discount structure – a call to IHD suggests that this distribution agency distinguishes between the two types of wholesalers. It has proven rather difficult to ascertain exactly what the discount structures are – access to pricing information is closely guarded.

[7] We do not consider here other services that wholesalers could develop in order to compete with the exclusive distribution agencies.

[8] Traditional wholesalers still buy from manufacturers that are not involved in the 'new' distribution arranagemts on the same terms as before – 17.5% discount.

[9] Glaxo Wellcome SA (Pty) Ltd, Pfizer Laboratoties (Pty) Ltd, Pharmacare Ltd – now Aspen Pharmacare, - SmthKline Beecham Pharmaceuticals (Pty) Ltd and Warner Lambert SA (Pty) Ltd. Two other manufacturers were also contracted to SAI – Janssen Pharmaceutica (Pty) Ltd and Merck (Pty) Ltd. Merck has since 27 March 2000 used PHD as its sole distribution agency – valid until March 2002.

[10] On the same terms as to wholesalers.

3. Assessment of competition impact: select issues

The three distribution arrangements, which currently exist alongside the traditional wholesale model, share a number of characteristics, but also differ in some respects. In the case of IHD, the arrangement may be characterised as a joint venture (JV). Since the JV involves several manufacturers in an exclusive distribution arrangement, the vertical relationship between the manufacturers and IHD is noted too. The vertical relationship in this case involves *joint ownership* of the distribution enterprise by the manufacturing firms.

Kinesis Logistics, whose holding company SAI is owned by five pharmaceutical manufacturers, was a joint venture, like IHD, until May 2001. SAI did however, unlike IHD, also distribute for two manufacturers, which were not owners of SAI, as well as for other parties as indicated above. SAI therefore involved differential modes of vertical integration; on the one hand an agency relationship and on the other joint ownership (as in the IHD case).

The formation of both IHD and SAI involved collective action by several manufacturers. This does not, however necessarily imply collusion, either tacit or explicit.[11] Both IHD and SAI, involve too, a measure of vertical integration in the sense of the involvement of two successive stages of production in the supply chain. The literature on vertical integration (see for example, Perry, 1989) , and especially that which deals with public policy towards vertical integration provides an array of support evidence, suggesting that in certain cases vertical integration may be benign and in others, have anti-competitive effects.

The Kinesis case takes an interesting turn earlier this year. One of the principals, Aspen Pharmacare (the only South African firm participating in this venture), has

[11] It is true that the initial discussions would have involved information sharing which may be held to have facilitated collusion. This is noteworthy with respect to the distinction between US anti-trust legislation and EU-type competition law – in the US *prima facie* would be required to prove collusion, this is not necessary in the EU.

openly expressed dissatisfaction with the Kinesis arrangement.[12] In May SAI (holding company of Kinesis Logistics) is sold to Tibbet & Britten SA (Pty) Ltd, a subsidiary of a multinational supply chain management enterprise. In terms of the sale agreement, Tibbett & Britton acquires the holding company SAI and will provide (exclusive) distribution services to Aspen Pharmacare and its fellow members of SAI, under separate contracts. This new arrangement is best characterised as an exclusive dealing arrangement.[13]

The third distribution arrangement, which has become known as the PHD case to the Competition Authorities, adds further interesting variations on the distribution theme. Pharmaceutical Health Distributors (Pty) Ltd is a logistics company, which in association with other companies provides distribution, warehousing, debt collection, batch tracking, order processing, picking , packing credit control and debt management to its principals. These companies are:

- Kite Logistics(Pty) Ltd, which transports pharmaceutical products to pharmacies and doctors.
- Order Pharm (Pty) Ltd which processes orders received from customers (wholesalers and pharmacies)
- Railit Total transportation (Pty) Ltd provides distribution and transport services of pharmaceutical products to the government and wholesalers.
- Recall (Pty) Ltd is responsible for debt management on behalf of PHD.

The PHD arrangement may also be characterised as an exclusive dealing arrangement. It's interesting to note that PHD and Recall are wholly owned subsidiaries of Fuel Logistics Holding Company Limited, which owns a 50% share of Kite. The other 50% shareholder of Kite is IHD!

[12] SA Druggists was party to the Kinesis arrangement. In March 1999, Aspen Pharmacare inherited a contractual obligation from SA Druggists to change its primary distribution channel to Kinesis in terms of agreements concluded by Pharmacare Limited before the acquisition of that company from SA Druggists They notes in their financial statements for six month period ended 31 December 2000, that the distribution fee to Kinesis 'gave rise to no commercial benefit' and that 'working capital levels were negatively affected' www.pharmacare.co.za/showarticle.php?id=108

[13] Mathewson and Winter (1987)

Competition issues arising from the new distribution arrangements

The complaints and applications for interim relief by the traditional wholesalers, that have been brought to the competition authorities, have attempted to show that the joint exclusive distribution arrangements constitute restrictive practices, either of a horizontal or vertical nature or involve abuse of a dominant position. These prohibited practices are covered by Chapter 2 of the Competition Act, No. 89 of 1998 (as amended). In support of their positions, the pharmaceutical manufacturers have advanced a range of pro-competitive arguments, citing efficiency gains, technology gains and the promotion of the public interest, as factors motivating the formation of the joint exclusive distribution enterprises, and countering claims of anti-competitive effects resulting from these arrangements. The arguments are specifically not reviewed here – Glynn (2000) presents a comprehensive catalogue of these.

We consider, instead, a selection of key questions to be contemplated in connection with competition concerns related to the joint exclusive distribution arrangements in pharmaceutical distribution.

Commercial interaction or anti-competitive behaviour?

This distinction, between commercial, competitive interaction and anti-competitive behaviour, is sometimes very difficult to draw. We need to recognise that competitive (commercial) interaction may result in smart moves by firms which may disadvantage[14] others (which may be in the same market as the smart mover, or a related one). Such competitive interaction need not necessarily raise competition concerns, quite the contrary in fact!

To illustrate this, consider some of the effects that have resulted from the formation of the distribution ventures. If we look at the entire pharmaceutical supply chain, then since the introduction of joint exclusive distribution ventures (whether exclusive dealing arrangements or vertical integration arrangements), the distribution of risk and transaction costs of doing business through the supply chain, has changed. In the traditional supply chain model, the wholesalers buy stock for their own account

[14] Disadvantage is used as a neutral term – not necessarily implying anti-competitive behaviour.

from manufacturers and on-sell to retailers. Retailers buy from wholesalers to meet consumer demand (reflecting their pharmacy or medical practice-specific demand profile). Wholesalers offer a flexible delivery service, with multiple deliveries per day, which facilitates minimal inventory holding by the individual pharmacy or medical doctor, thus minimising risk or theft, (with implication for insurance costs), mismatches between demand and supply, and mitigating the costs of high levels of inventory holding (investment in inventory).

The new distribution model, joint exclusive distribution, offers, for example, less frequent deliveries to retailers. IHD does not guarantee same-day delivery, except in exceptional circumstances. This means that retailers have to hold more stock – with an associated increase in risk and in other transaction costs of doing business. The key question is - does this raise competition concerns or does it merely reflect the outcome of commercial, competitive interaction? From a South African competition policy perspective, we need to reflect on a number of issues here, including:

- specific concerns about *small and medium-sized firms* expressed in the Competition Act (and along with that, we need to consider the size distribution of firms through the supply chain – there seems to be a cascading distribution, with larger firms upstream and smaller firms at the retail end of the supply chain)

- *public interest* implications of these changes eg impact on the consumer especially in so far as accessibility, availability and price of prescription drugs are concerned.[15]

[15] Price effects have been considered by the Competition Authorities and evidence is not entirely clear – causality confusion is often in such cases a problem. It is perhaps instructive that the CEO of SAI, on its formation, remarked that price decreases would not necessarily result from the joint exclusive distribution venture. This is merely suggestive, but nonetheless indicative of the fact that an assessment of efficiency gains needs to go beyond price effect.

Exclusive dealing

A distinctive feature of all the arrangements considered, is an *exclusivity clause,*[16] which each manufacturer enters into with the distribution enterprise. In all cases, to our knowledge, the exclusivity clause is time-bound.

The perspective from the competition authorities, is that exclusivity may not be a concern, but the joint nature of an arrangement should be examined to determine whether horizontal collusion exists.[17]

The extensive body of literature on exclusive dealing offers a range of perspectives, some emphasising the potential for efficiency enhancement specifically in the form of lower prices, (Mathewson and Winter, 1987), even when the market is foreclosed to one of the manufacturers in a duopoly model. A contrasting view comes from Krattenmaker and Salop (1986). They argue that exclusionary contracts are frequently designed to raise rivals' costs and so deter competition. Accordingly, there are situations where exclusive dealing contracts have a purely strategic purpose, with few if any compensating efficiencies. These results need to be reflected upon in each specific case.

Another issue that is pertinent to the exclusive dealing arrangement, is whether or not the vertical arrangement veils a horizontal relationship between competitors. On this score, the competition authorities have held that evidence of actual collusion is required – conjecture, mere suggestion or facilitating circumstances are not proof enough. *Prima facie* evidence, as would be required in US anti-trust cases, seems to be necessary for such a conclusion. To date this has not been garnered in any relevant case.

[16] A game theoretic argument may be considered here – in a Nash Equilibrium, this clause would be superfluous, casting doubt on the purported efficiency support for its inclusion.

[17] In Tribunal Case No. 68/IR/Jun00, it is suggested that exclusivity does not necessarily contravene the Competition Act – but that the joint nature of the agreement (joint ownership in the case of IHD) implied horizontal collusion, and interim relief was granted to the applicants.

Agency or Ownership – does it make a difference?

Does ownership of the distribution venture differ materially from an agency relationship between manufacturers and the distribution enterprise, from a competition perspective? Neither ownership nor an agency relationship *per se*, is *sufficient* to prove a restrictive practice – the one is merely a weaker form of vertical integration than the other (Case No. 98/IR/Dec00 – Competition Tribunal).[18] And vertical integration may be associated with either pro-competitive or anti-competitive effects.

Inherent in the conception of vertical integration is the elimination of market exchanges, and the substitution of internal exchanges within the boundaries of the firm. Definitional certainties are required when assessing agency as opposed to ownership concerns – does the specific exclusive agency agreement eliminate market exchange? We also need to consider the definition of a single economic entity for competition policy purposes (see footnote 20).

Analysis of principal-agent relationships suggests that ownership may indeed reduce transaction costs and lower specific risk [19] – thus producing efficiency gains; however it may also facilitate collusion! Matters of ownership and control[20], thus need careful analysis to identify any pro-competitive and anti-competitive effects, noting the conclusions of a series of indistinguishability theorems (is it collusion or is it competition?) in the industrial organisation literature, and their implications for the operation of competition policy.[21]

[18] The transaction cost literature notes a range of efficiency gains associated with vertical integration eg asset specificity (this argument has been put forward by manufacturers as regards investment in distribution infrastructure), adaptation to uncertainty, risk and complexity (this is relevant in the context of changes such as generic substitution and parallel imports)

[19] Effective transfer of information between manufacturer and distributor, is an example.

[20] It may also be of interest to note the decision of the competition authorities concerning 'the single economic entity' in the Distillers case, in this regard.

[21] Unless competition authorities have access to an implausible amount of information, it is impossible to tell, for example if simultaneous price movements are the result of collusion or simply reactions to exogenous demand shifts. Submission to the Tribunal (Case No. 53/IR/Apr00) has held that the fact that SAI principals offer different discount structures, implies that they are not colluding. The indistinguishability argument puts paid to that submission.

Impact on the nature and extent of competition

In an overall assessment of the impact on competition, two types of competition are relevant to consider here: inter-brand and intra-brand competition[22]. As regards intra-brand competition, the impact of the establishment of the distribution enterprises on the sources (availability) of specific drugs is relevant. Wholesalers have argued (Competition Tribunal Case No. 98/IR/Dec00) that the establishment of exclusive joint distribution enterprises reduces the distribution channel options of the relevant products, and as a result intra-brand competition is reduced. This argument is intuitively appealing, however, in the case where exclusivity is partial in the sense that it is mediated by the a reduced discount structure (down from 17.5% to 11-13%) for wholesalers, in the case of AstraZeneca *(ibid*), as opposed to a complete elimination of the wholesale discount as is the case with IHD, then the conclusion is not as obvious. It may be argued that the lower discount still facilitates a distribution role for traditional wholesalers (and an incentive to reduce their costs so as to be able to compete on price with the joint exclusive distribution agency, as well as engage in non-price competition). Conclusions therefore hinge of the extent of the discount offered to traditional wholesalers, and in turn their possibilities for lowering costs, and engaging in non-price competition.

The extent of inter-brand competition depends on the own price elasticity of demand as well as cross-price elasticities of demand. The availability of substitutes for a particular drug and the prescribing preferences of medical doctors are important considerations (and these will be influenced by generic substitution and parallel imports). We should also consider competition among manufacturers within a specific exclusive distribution arrangement (intra-arrangement) and that among manufacturers belonging to different distribution arrangements (inter-arrangement competition). It may be true that competition within an arrangement is subdued by the joint exclusive distribution arrangement, but it is possible that simultaneously, inter-arrangement competition among competing brands may increase. The analysis has, of course, to be done for specific therapeutic

[22] Intra-brand competition is product specific, arising when a product is available from different sources. Inter-brand competition arises with substitution possibilities – consumers have a choice of different brands of products that perform the same function.

categories to draw sensible conclusions. The question then is, on balance, what is the effect on inter-brand competition?

An overall assessment of the competition impact should balance considerations relevant to both intra-brand and inter-brand competition before drawing any conclusions.

4. Conclusion

The changes in modes of pharmaceutical distribution that have developed during the past decade, have changed the configuration of the South African pharmaceutical supply chain in a number of respects. These changes, which have been motivated and initiated by groups of pharmaceutical manufacturers, have led to a series of hotly contested competition cases, both applications for interim relief and complaints. Decisions have gone both ways – in some cases in favour of wholesalers and others in favour of manufacturers, and or their exclusive distribution ventures. This is not proof of confusion on the part of the competition authorities, but highlights the intricacies of assessment of the competition impact of these distribution arrangements.

This paper has not reviewed the competition decisions, but rather sought to raise a selection of key issues which a foray into the industrial organisation and competition policy literature offers insight into. *As we've seen the insights do not provide unambiguous guidance for an assessment of the competition impact of the joint exclusive distribution activities.* This is where the interface between law and economics, and the interaction between lawyers and economists adds an interesting dimension. The saga continues with another case currently before Competition Tribunal… on the one hand…. but, then on the other hand… a typical economist's tale….

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